

EPA REGISTRATION NUMBER 33025-6

PROCESSING REQUEST

Reg # 33025-6

Decision # 546225 and 549337

Description: Amendment/Notification - Changing the name of the active ingredient and adding optional marketing claims and sublabel for trial size bottle co packaged with trial PvcL.

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 06/27/19

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSI(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer:

Menya Adams
BPPD

Division:

Phone:

703-347-8496

Date:

06/27/19



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

June 27, 2019

Georgia Anastasiou, Agent
Lamplight Farms, Inc.
c/o Lewis & Harrison, LLC
2461 S. Clark St., Suite 710
Arlington, VA 22202

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment -- Changing the name of the active ingredient and Adding optional marketing claims and sublabel for trial size bottle co packaged with table torch.
Product Name: CleanBurn
EPA Registration Number: 33025-6
Application Dates: 11/16/2018 and 03/05/2019
OPP Decision Numbers: 546225 and 549337

Dear Ms. Anastasiou:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration

Page 2 of 2
EPA Reg. No. 33025-6
OPP Decision No. 546225 and 549337

process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Menyon Adams by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew C. Bryceland".

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

[Bracketed Text] = Optional Language

Note: **Bold, italicized text** is information for the reviewer and is not part of the label.

CLEANBURN

EPA Reg. No. 33025-6

Master Label

CLEANBURN

Torch Fuel

ACCEPTED

06/27/2019

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended for the
pesticide registered under
EPA Reg. No. 33025-6

**[Alternate Brand Names: TIKI Brand Paradise In Your Backyard Clean Burn with Citronella,
TIKI Brand Paradise in Your Backyard Clean Burn BiteFighter Torch Fuel]**

Active Ingredient:

Oil of Citronella*..... 3%

Other Ingredients 97%

Total..... 100%

* Contains no less than 0.56% geraniol

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS: [0.25pt/4 fl oz (118mL)] [0.5pt/8 fl oz (236.5mL)] [0.75pt/12 fl oz
(354.8mL)] [1pt 2 fl oz/18 fl oz (532mL)] [1qt/32 fl oz (946mL)] [1qt 18 fl oz/50 fl oz
(1.48L)] [2qt/64 fl oz (1.89L)] [3qt 4 fl oz/100 fl oz (2.96L)] [1 gal/128 fl oz (3.78L)]
[1 table torch; 1 bottle of fuel .25pt/4 fl oz (118 mL)] [1 table torch; 1 bottle of fuel .5pt/8
fl oz (236.5 mL)]

[Product of Singapore Blended and Bottled in the USA]

[Table torch: Made in [China][India][Mexico] [Cambodia], Fuel: product of Singapore, bottled in the USA]

Lamplight Farms Inc.

W140 N4900 Lilly Road

Menomonee Falls, WI 53051-7035

EPA Reg. No. 33025-6

EPA Est. No. 33025-WI-001

©20##

Read [Entire Label] [All Warnings] [Back Panel] [Bottom Panel] CAREFULLY.

**[KEEP OUT OF REACH OF CHILDREN AND PETS.] [NEVER LEAVE A BURNING TORCH
UNATTENDED.] [FAILURE TO FOLLOW INSTRUCTIONS MAY RESULT IN SERIOUS INJURY OR
PROPERTY DAMAGE.] [DO NOT DRINK.]**

Batch code_____

EPA Label amended label 06/20/2019

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling product and before eating, drinking, chewing gum, using tobacco or using the toilet. **KEEP OUT OF REACH OF CHILDREN [AND PETS].**

First Aid

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Environmental Hazards

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

[Physical or Chemical Hazards

△ **[NOTICE:** This product and combustion products emitted when this product is burning can expose you to chemicals including soot, which is known to the State of California to cause cancer. For more information go to www.P65warnings.ca.gov.] [Contains plant based Methyl Esters.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR USE ONLY. Remove cap. Pour directly from bottle into [vessel], [canister], [burner]. [Store and dispense fuel from original container into vessel.] Wipe away excess fuel before lighting. Replace cap [after each use to prevent accidental ingestion.] [Failure to follow warnings and instructions may result in serious injury or property damage.] [DO NOT use product under the influence of drugs or alcohol] [DO NOT add fuel to burner when it is burning or hot.] [IMPORTANT: DO NOT allow fuel to come in contact with any surface.] [Fuel may damage plastic and other finishes.] Follow all torch manufactures instructions for use. [Retain these instructions for future use].

STORAGE AND DISPOSAL

Pesticide Storage: Store upright, away from heat or open flame. **Container disposal: If empty:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Optional Marketing Claims

- Proven Mosquito Repellency
- [Keeps mosquitoes away]
- [Filled with citronella [torch fuel]]
- [Perfect for use [in backyards] [around pools]]
- [Burns for hours]

Optional Marketing Claims - continued

- [[For best results] use one or more torches in still air]
- [[Torch] Fuel cartridge [bottle] [container]]

- [Contains citronella [torch] [fuel]]
- [[Repels mosquitoes, [gnats] and other [flying] insects]
- [Repels mosquitoes]
- [Citronella torch fuel]
- [Plant Based* *85% Plant Based]
- [Petroleum Free]
- [No More Smoky Mess!]
- [[Create] [A] [Convenient] Paradise In Your Backyard]
- [For use in TIKI® Brand torches]
- [[For best results] Use in TIKI® brand torches]
- [For best results use several torches [around an area] [to surround an area] [throughout your backyard]]
- [[For best results] [properly] refill torch canister when it is 2/3 empty]
- [No Smoky Mess]
- [Traditional Tabletorch & Fuel]
- [Clean Burn]
- [TIKI® Brand Clean Burn System]
- [[Trial] Fuel Included]
- [Includes [Trial] Fuel [Trial]]
- [X Hours of Fuel Included]
- [Comes with [Clean Burn™ Torch] Fuel]
- [Keep[s] away uninvited guests [that buzz and bite]]
- [Slapping a mosquito is great. Not having to is better]
- [Dramatically less [soot] [and] [smoke]]
- [Repel mosquitos. Attract guests]
- [Reclaim your backyard]
- [Do not let mosquitos share your yard this year]
- [Invite the neighbors uninvite the mosquitos]
- [Inviting guests also requires uninviting mosquitos]
- [It's time to take back your yard]
- [Take back your backyard]
- [Sharing a meal is better than being one]
- [Declare your yard a no-fly zone]
- [Don't let mosquitos ruin a perfectly good sunset]
- [[It is] [It's] like an unwelcome mat for mosquitos]
- [Because mosquitos can't read a no trespassing sign]
- [Sorry mosquitos, invitation only]
- [Invite family, not mosquitos]
- [Invite friends, not mosquitos]
- [Let mosquitos know they [are not] [aren't] welcome]
- [Stop sharing your yard with mosquitos]
- [Avoid mosquitos, not the backyard]
- [Mosquitos, this is your eviction notice]
- [The best kept secret to outdoor entertaining]
- [Share an evening with friends. Not Mosquitos]
- [Take a holiday from mosquitos.]
- [Keep mosquitos far[, far, far, far, far] away.]
- [How backyards fight back.]
- [Keep away hungry mosquitos[with Clean Burn BiteFighter Torch Fuel.]]
- [Protect your yard against mosquitos.]
- [Clean Burn BiteFighter repels mosquitoes, so you can give your blood to a better cause.]
- [Don't be dinner.] [Keep mosquitos far away].
- [Your family isn't an all-you-can-eat buffet.] [Keep mosquitos far away.]

- [Your ankles aren't appetizers.] [Keep mosquitos far away.]
- [Mosquitos are jerks.] [Keep mosquitos far away with Clean Burn BiteFighter Torch Fuel.]
- [Mosquitos are jerks.] [Mosquitos think it's ok to lay 300 eggs in your kiddie pool.] [All the more reason to keep them away.]
- [Mosquitos are jerks.] [Mosquitos bite you in the face, making it look like you have a zit.] [All the more reason to keep them away.]
- [Mosquitos are jerks.] [Mosquitos bite you so they can give birth to more mosquitos that will bite you.] [All the more reason to keep them away.]
- [Mosquitos are jerks.] [Mosquitos never thank you for dinner.] [All the more reason to keep them away.]
- [Mosquitos are jerks.] [Mosquitos ruin all the prettiest sunsets.] [All the more reason to keep them away.]
- [It's a great big world out there.] [Make sure your grad doesn't get eaten alive.] [Celebrate and keep mosquitos away.]
- [Stock up on mesquite, not mosquitos.] [Cook out on Memorial Day and keep mosquitos away.]
- [Mosquitos like you medium rare.] [Cook out on Memorial Day and keep mosquitos away.]
- [Your mom doesn't need anything else sucking the life out of her.] [Celebrate Mother's Day and keep mosquitos away.]
- [No more mosquitos. No more socks with sandals.] [Celebrate Father's Day with exposed ankles.]
- [The mosquitos are coming! The mosquitos are coming!] [Celebrate 4th of July and keep mosquitos away.]
- [Don't get 1,116 mosquito bites.] [Celebrate 4th of July and keep mosquitos away.]
- [See ya suckers.] [How backyards fight back.] [Clean Burn BiteFighter Torch Fuel provides proven mosquito repellency.]
- [Adios mosquitos.] [How backyards fight back.] [Clean Burn BiteFighter Torch Fuel provides proven mosquito repellency.]
- [Beat it skeeters.] [How backyards fight back.] [Clean Burn BiteFighter Torch Fuel provides proven mosquito repellency.]
- [Buzz off.] [How backyards fight back.] [Clean Burn BiteFighter Torch Fuel provides proven mosquito repellency.]

[Questions or comments Call 1-888-473-1088] [or visit our website at www.tikibrand.com.]

[Customer service 1-888-473-1088]

[Tiki® & Clean Burn™ are trademarks of Lamplight Farms Inc.]

Sub-label A – Trial Size Fuel Bottle sold with a Tiki Torch

Not for individual retail sale – Bottle will be packaged within secondary package along with torch. Required and selected optional master label content will be presented on or included with secondary package. Due to the small package size, reduced labeling content will be included on the trial sized fuel bottle as described in chapter 18 of the EPA Label Review Manual. Minimum content that will be included listed below. Other text from the master label may be included.

[CLEAN BURN TORCH FUEL]

[***Alternate Brand Names:*** [TIKI Brand Paradise In Your Backyard Clean Burn with Citronella]
[TIKI Brand Paradise in Your Backyard Clean Burn BiteFighter Torch Fuel]]

Active Ingredient:

Oil of Citronella*	3%
Other Ingredients	97%
Total	100%

* Contains no less than 0.56% geraniol

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read [Entire Label] [All Warnings] [Back Panel] [[Instructions] [Precautionary Material] [Directions for Use]
[Included [With] [In] [on] [Packaging] CAREFULLY.

EPA Reg. No. 33025-6
EPA Est. No. 33025-WI-001,
©20##

OPTIONAL LANGUAGE that will appear on the torch

[TIKI Brand Paradise in your backyard [glass] [metal] [bamboo] [ceramic] [garden]
[table] [tabletop] torch] [outdoor table torch]

[Product of Singapore Blended and Bottled in the USA]
[Table torch: Made in [China][India][Mexico] [Cambodia], Fuel: product of Singapore, bottled in the USA]
Lamplight Farms Inc.
W140 N4900 Lilly Road
Menomonee Falls, WI 53051-7035
EPA Reg. No. 33025-6
EPA Est. No. 33025-WI-001

[CAUTION]

[DO NOT use product while under the influence of drugs or alcohol]
[Keep out of reach of children and pets]
[For outdoor [tabletop] use only]
[Read complete instructions [and warnings] provided with product [prior to use]]
[DO NOT move vessel while burning]

[NEVER leave a flame unattended]

[Read warnings on torch fuel container carefully]

[Read torch fuel warnings carefully]

[NEVER leave a burning torch unattended] [Failure to follow warnings and instructions may result in serious injury or property damage]

[Use only TIKI Brand Fuels – DO NOT use gasoline or other flammable fuels]

[Use only in well-ventilated area. Do not use in windy conditions]

[Use only TIKI Brand Wicks]

[DO NOT tip torch as fuel can spill and cause fire or serious injury]

[DO NOT place torch under covered shelter or umbrellas, near pedestrian traffic or combustibles] [such as] [wood structures] [fuel] [clothing] [or] [vegetation].

[Instructions for use:]

[INSTALLING:] [Place on temperature safe surface.]

[FILLING] [Unscrew metal cap and wick assembly from the torch and fill with TIKI Brand Torch Fuel.] [Fill torch ½" from top] [DO NOT OVERFILL.] [Reattach metal cap and wick assembly to torch.] [DO NOT OVERTIGHTEN.]

[LIGHTING:] [Wipe away any spilled fuel before lighting.] [Allow wick to become saturated with fuel.] [Exposed wick should be no higher than ½" [3/4"] [Keep clothing, hair and face away from flame when lighting.]

[EXTINGUISHING:] [Using the snuffer cap that is attached to the torch, carefully place completely over wick until flame is extinguished.] [Place snuffer cap over wick to protect from elements.] [Allow to cool for 30 minutes before handling and refilling]

[©20xx Lamplight Farms Inc., [W140 N4900 Lilly Rd.,] Menomonee Falls WI 53051]

[Tiki® & PARADISE IN YOUR BACKYARD are trademarks of Lamplight Farms Inc.]

[Customer Service: 1-888-473-1088]

[Bracketed Text] = Optional Language

Note: ***Bold, italicized text is information for the reviewer and is not part of the label.***

CLEANBURN

EPA Reg. No. 33025-6

Sub-label B – Trial Size Fuel Bottle

not for individual retail sale –Due to the small package size, reduced labeling content will included on the trial sized fuel bottle as described in chapter 18 of the EPA Label Review Manual. Minimum content that will be included listed below. Other text from the master label may be included.

[CLEAN BURN TORCH FUEL]

[Alternate Brand Names: [TIKI Brand Paradise In Your Backyard Clean Burn with Citronella]

[TIKI Brand Paradise in Your Backyard Clean Burn BiteFighter Torch Fuel]

Active Ingredient:

Oil of Citronella*..... 3%

Other Ingredients 97%

Total..... 100%

* Contains no less than 0.56% geraniol

KEEP OUT OF REACH OF CHILDREN

CAUTION

Read [Entire Label] [All Warnings] [Back Panel] [(Instructions)] [Precautionary Material] [Directions for Use]
[Included [With] [In] [on] [Packaging] CAREFULLY.

EPA Reg. No. 33025-6

EPA Est. No. 33025-WI-001,

©20##

Receipt for Section 3

S. 1032308

Milestone Email: cswick@lewisharrison.com

Regulatory Type Product Registration - Section 3

Application Type: Amendment

Company: 33025 LAMPLIGHT FARMS. INC

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 33025-6

Product Name: Cleanburn

Me Too
Section3

Me Too Product
Name.

Application Date: 05-Mar-2019



OPP Rec'd Date: 05-Mar-2019



Front End Date: 20-Mar-2019



Risk Manager Send Date: 26-Mar-2019



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track ☒ New Ingredient ☐

Receipt Description:

Portal submission pkg# 37130 Fast Track Non-PRIA Label Amendment

Print Letter

Enter More Information

Tracking

Fee For Service: ☐ Yes ☒ No

Billable: ☐ Yes ☒ No

V

Receipt Content

Electronic Label

View/Edit

Mcayon

549337



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

March 26, 2019

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

CHRISTINA SWICK
LEWIS & HARRISON, LLC
LAMPLIGHT FARMS, INC.
2461 SOUTH CLARK STREET, SUITE 710
ARLINGTON, VA 22202-

PRODUCT NAME: Cleanburn
COMPANY NAME: LAMPLIGHT FARMS, INC.
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 33025-6
EPA RECEIPT DATE: 03/05/19

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at 703-305-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "AL" or similar, written over a horizontal line.

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

Fee for Service

{10323086~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies? ☐ Fee Waiver?
- ☐ volpay % Reduction: _____

for Division

- ☐ AD
- ☒ BPPD
- ☐ RD

Risk Mgr. 91

Receipt No.

S-

1032308

EPA File Symbol/Reg. No.

33025-6

Pin-Punch Date:

3/5/2019

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

300

Granted:

300

Amount Due: \$ _____

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Gina Burnett

Date: 3/25/2019

Remarks:

DOCUMENTUM

LEWIS & HARRISON

Consultants in Government Affairs

2461 S. Clark St., Suite 710
Arlington, VA 22202
telephone 202.393.3903
fax 202.393.3906

March 5, 2019

E-Submission

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: **Andrew Bryceland**
 Biopesticides and Pollution Prevention Division

SUBJECT: **Lamplight Farms, Inc.**
 CLEANBURN (EPA Reg. No. 33025-6)
 Non-PRIA - Minor Label Amendment

Dear Mr. Bryceland:

On behalf of Lamplight Farms, Inc., I am submitting a minor label amendment for the product CLEANBURN (EPA Reg. No. 33025-6). The purpose of this amendment is to:

- Add an Environmental Hazards statement as requested by the California Department of Pesticide Regulation;
- Add optional marketing language; and,
- Add sub-labels for trial size bottles and bottles co-packaged with table torches.

Enclosed please find the following documents in support of this submission:

- A. Application for Pesticide Form; and,
- B. PDF copy of the label with changes highlighted
- C. PDF copy of the revised label.

If you have any questions, or require any additional information, please feel free to contact me at 202-393-3903 ext. 116 or cswick@lewisharrison.com.


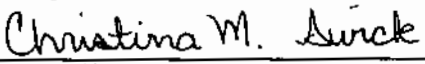
Sincerely,

Christina M. Swick

Christina M. Swick
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)

DOCUMENT

 EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input checked="" type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 33025-6		2. EPA Product Manager Andrew Bryceland	
4. Company/Product (Name) CLEANBURN		PM# BPPD <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Lamplight Farms, Inc. c/o Lewis & Harrison, LLC 2461 S. Clark St., Suite 710 Arlington, VA 22202 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name: _____	
Section - II			
<input checked="" type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input type="checkbox"/> Notification - Explain below. <input type="checkbox"/> Other - Explain below			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) <div style="text-align: center;">Non-PRIA Label Amendment (see cover letter for details)</div>			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2- 128 fl. oz.	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Christina Swick, Lewis & Harrison, LLC,		Title Agent Telephone No. (Include Area Code) 202-393-3903 x. 116	
Certification		6. Date Application Received (Stamped)	
I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			
2. Signature 			
3. Title Agent			
4. Typed Name Christina Swick		5. Date March 5, 2019	

DOCUMENTUM

S: 1027664

Milestone Email: georgia@lewisharrison.com

Regulatory Type: Product Registration - Section 3

Application: ☐ New ☒ Existing

Print Letter

Application Type: Notification

Fee For Service: ☐ Yes ☒ No

Enter More Information

Company: 33025 LAMPLIGHT FARMS, INC.

V

Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 33025-6

Product Name: Cleanburn

Me Too

Section3:

Me Too Product
Name:

Application Date: 16-Nov-2018



OPP Rec'd Date: 16-Nov-2018



Front End Date: 20-Nov-2018



Risk Manager Send Date: 20-Nov-2018



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Form Fee ☐ Label Fee ☐ Receipt Fee ☐ New Ingredient ☐

Receipt Description:

Portal submission pkg# 34406 Label notification changes per pm 98-10 Change name of ai

Receipt Content

Des

Electronic Label

View/Edit

Jandra

5-14-2015

M. J. J.

LEWIS & HARRISON

2461 S. Clark St., Suite 710
Arlington, VA 22202

telephone 202.393.3903
fax 202.393.3906

Consultants in Government Affairs

November 16, 2018

E-Submission

Document Processing Desk (NOTIF)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: **Andrew Bryceland**
 Biopesticides and Pollution Prevention Division

SUBJECT: **Lamplight Farms, Inc.**
 CLEANBURN (EPA Reg. No. 33025-6)
 Notification per PR Notice 98-10

Dear Mr. Bryceland:

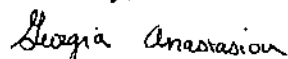
On behalf of Lamplight Farms, Inc., I am submitting a notification for the product CLEANBURN (EPA Reg. No. 33025-6). The purpose of this notification is to change the name of the active ingredient from "Citronella Oil" to "Oil of Citronella". These common names are used interchangeably for this active ingredient and are both listed in the OPPIN database.

Enclosed please find the following documents in support of this submission:

- A. Application for Pesticide Form; and,
- B. PDF copy of the label with changes highlighted
- C. PDF copy of the revised label.


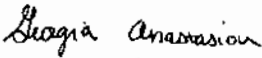
If you have any questions, or require any additional information, please feel free to contact me at 202-393-3903 ext. 119 or georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)

 EPA United States Environmental Protection Agency Washington, DC 20460		<input type="checkbox"/> Registration <input type="checkbox"/> Amendment <input checked="" type="checkbox"/> Other:	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 33025-6		2. EPA Product Manager Andrew Bryceland	
4. Company/Product (Name) CLEANBURN		PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Lamplight Farms, Inc. c/o Lewis & Harrison, LLC 2461 S. Clark St., Suite 710 Arlington, VA 22202 <input type="checkbox"/> Check if this is a new address		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name: _____	
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Notification - Explain below. <input type="checkbox"/> Other - Explain below			
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) Notification is to change the name of the active ingredient from "Citronella Oil" to "Oil of Citronella" <i>This notification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the labeling or the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this notification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA</i>			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2- 128 fl. oz.		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Georgia Anastasiou, Lewis & Harrison, LLC,		Title Agent	Telephone No. (Include Area Code) 202-393-3903 x. 119
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Georgia Anastasiou		5. Date November 16, 2018	

PROCESSING REQUEST

Reg # 33075-6

Decision # 534726

Description: New Product

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 08/17/18

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☒ New CSF(s) Dated: 02/06/2018

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: Mengya Adams

Division: BPPD

Phone: 703-347-8492

Date: 08/17/18



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

33025-6

Date of Issuance:

8/17/2018

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration
(under FIFRA, as amended)

Term of Issuance:

Unconditional

Name of Pesticide Product:

Cleanburn

Name and Address of Registrant (include ZIP Code):

Lamplight Farms, Inc.
4900 North Lilly Road
Menomonee Falls, Wisconsin 53051

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act).

Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under the Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) provided that you:

1. Submit and/or cite all data required for registration or registration review of your product when the EPA requires all registrants of similar products to submit such data.
2. Make the following labeling change before you release this product for shipment:
 - Revise the EPA Registration Number to read, "EPA Reg. No. 33025-6."

Signature of Approving Official:

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

Date:

8/17/2018

3. Submit one (1) copy of the final printed labeling for the record before you release this product for shipment.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6. A stamped copy of the labeling is enclosed for your records. Please also note that the record for this product currently contains the following acceptable Confidential Statements of Formula (CSFs):

- Basic CSF dated 02/06/2018
- Alternate CSF #1 dated 02/06/2018

Any CSFs other than those listed above are superseded.

If you have any questions, please contact Menyon Adams of my team by phone at (703) 347- 8496 or via email at adams.menyon@epa.gov.

Sincerely,



Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

[Bracketed Text] = Optional Language

Note: ***Bold, Italicized text is information for the reviewer and is not part of the label.***

CLEANBURN

EPA Reg. No. 33025-A

Master Label

CLEANBURN

Torch Fuel

[Alternate Brand Names: TIKI Brand Paradise In Your Backyard Clean Burn with Citronella,
TIKI Brand Paradise In Your Backyard Clean Burn BiteFighter Torch Fuel]

Active Ingredient:

Citronella Oil* 3%

Other Ingredients 97%

Total 100%

* Contains no less than 0.56% geraniol

KEEP OUT OF REACH OF CHILDREN

CAUTION

ACCEPTED

08/17/2018

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 33025-6

NET CONTENTS: [1pt 2 fl oz/18 fl oz (532mL)] [1qt/32 fl oz (946mL)] [1qt 18 fl oz/50 fl
oz (1.48L)] [2qt/64 fl oz (1.89L)] [3qt 4 fl oz/100 fl oz (2.96L)] [1 gal/128 fl oz (3.78L)]

Product of Singapore, Blended and Bottled in the USA
Lamplight Farms Inc.
W140 N4900 Lilly Road
Menomonee Falls, WI 53051-7035

EPA Reg. No. 33025-A

EPA Est. No.

©2011

Read [Entire Label] [All Warnings] [Back Panel] CAREFULLY.

**[KEEP OUT OF REACH OF CHILDREN AND PETS.] [NEVER LEAVE A BURNING TORCH
UNATTENDED.] [FAILURE TO FOLLOW INSTRUCTIONS MAY RESULT IN SERIOUS INJURY OR
PROPERTY DAMAGE.] [DO NOT DRINK.]**

Batch code _____

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

CAUTION: Causes moderate eye irritation. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and water after handling product and before eating, drinking, chewing gum, using tobacco or using the toilet. **KEEP OUT OF REACH OF CHILDREN [AND PETS].**

First Aid

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing. Call a poison control center or doctor for treatment advice.

If on Skin: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

Physical or Chemical Hazards

⚠ NOTICE: This product and combustion products emitted when this product is burning can expose you to chemicals including soot, which is known to the State of California to cause cancer. For more information go to www.P65warnings.ca.gov. [Contains plant based Methyl Esters.]

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

FOR OUTDOOR USE ONLY. Remove cap. Pour directly from bottle into [vessel], [canister], [burner]. [Store and dispense fuel from original container into vessel.] Wipe away excess fuel before lighting. Replace cap [after each use to prevent accidental ingestion.] [Failure to follow warnings and instructions may result in serious injury or property damage.] [DO NOT use product under the influence of drugs or alcohol] [DO NOT add fuel to burner when it is burning or hot.] [IMPORTANT: DO NOT allow fuel to come in contact with any surface.] [Fuel may damage plastic and other finishes.] Follow all torch manufactures instructions for use.

STORAGE AND DISPOSAL

Pesticide Storage: Store upright, away from heat or open flame. **Container disposal: If empty:** Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. **If partly filled:** Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

Optional Marketing Claims

- Proven Mosquito Repellency
- [Keeps mosquitoes away]
- [Filled with citronella [torch fuel]]
- [Perfect for use [in backyards] [around pools]]
- [Burns for hours]
- [[For best results] use one or more torches in still air]
- [[Torch] Fuel cartridge [bottle] [container]]
- [Contains citronella [torch] [fuel]]
- [Repels mosquitoes, [gnats] and other [flying] insects]
- [Repels mosquitoes]
- [Citronella torch fuel]
- [Plant Based* *85% Plant Based]
- [Petroleum Free]

Optional Marketing Claims - continued

- [No More Smoky Mess!]
- [[Create] [A] [Convenient] Paradise In Your Backyard]
- [For use in TIKI® Brand torches]
- [[For best results] Use in TIKI® brand torches]
- [For best results use several torches [around an area] [to surround an area] [throughout your backyard]]
- [[For best results] [properly] refill torch canister when it is 2/3 empty]
- [No Smoky Mess]
- [Traditional Tabletorch & Fuel]
- [Clean Burn]
- [TIKI® Brand Clean Burn System]

[Questions or comments Call 1-888-473-1088] [or visit our website at www.tikibrand.com.]

[Customer service 1-888-473-1088]

[Tiki® & Clean Burn™ are trademarks of Lamplight Farms Inc.]

DDP Old Active Ingredient Checklist

New Product Registration/Existing Product Amendment

Fast Track ☐ PRIA Actions B650 ☐, B660 ☐, B670 ☐, B680 ☐, B710 ☐, B720 ☐, B730 ☐, B880 ☐ & B900 EPA

33025.6

Reg. No.:

RAL: *Machin*

Application Date:

x	Check list Item	Yes	No
1.	Application Form (EPA Form 8570-1) - signed & complete including package type? IF NO, STOP! Call applicant and have them correct application and resubmit.	<input checked="" type="checkbox"/>	
2.	If amendment, was final printed labeling received for previous action? IF NO, STOP! E-mail applicant and request final printed labeling.		
3.	Confidential Statement of Formula (CSF) EPA Form 8570-4 Basic Formula <input checked="" type="checkbox"/> 1 Alternate Formula(s) <input type="checkbox"/>	<input checked="" type="checkbox"/>	
a.	CSF Review completed? IF YES, SKIP to ITEM 4.	<input checked="" type="checkbox"/>	
b.	CSF is signed and dated? IF NO, CALL APPLICANT.	<input checked="" type="checkbox"/>	
c.	Completely filled out: CAS numbers, pH, flashpoint, flammability, if applicable?	<input checked="" type="checkbox"/>	
d.	Are the totals accurate?	<input checked="" type="checkbox"/>	
e.	Certified limits agree with 40 CFR 158.175? Note that if preliminary or 5 batch analysis differ from Section 158.175(b), limits based on batch analysis would need to be proposed under Section 158.175(c).	<input checked="" type="checkbox"/>	
f.	Viability (if live microbial, i.e., cfu/gram)? NA <input checked="" type="checkbox"/>		
g.	PC codes assigned on CSF for actives & inerts plus 40 CFR 180.910, 180.920, and 180.930 codes noted for products that have food or feed uses?	<input checked="" type="checkbox"/>	
h.	List 1 inert ingredient(s) present in the formulation? If YES, be sure it is listed on the label.		<input checked="" type="checkbox"/>
i.	Alternate formula(s) do not require different labeling from basic CSF or other alternate CSFs per 40 CFR 152.43(b)(3). NA <input type="checkbox"/>	<input checked="" type="checkbox"/>	
j.	Source for a.i. is a registered pesticide? (When a proposed alternate or new basic formula involves a new registered manufacturing-use product as the active ingredient source it must be determined whether the manufacturing-use products used to formulate are similar enough to warrant use of existing product specific data such as acute toxicity.)	<input checked="" type="checkbox"/>	
k.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES, RAL must evaluate label directions for compliance with 40 CFR 180.1071.		<input checked="" type="checkbox"/>
4.	Data and Data Matrix present. (EPA Form 8570-35)	<input checked="" type="checkbox"/>	
a.	a) Using Selective Method? [IF NO, SKIP to ITEM 5 since data matrix required for selective method.]		
b.	Complete Data Matrix supporting both the product registration and, if applicable, the proposed amendment. Minimum Data Matrix for registration includes: product specific acute toxicity, product chemistry, and efficacy data for public health pests claimed on label.		
c.	Adequate product specific data submitted?		
d.	Registered source used for active ingredient? IF YES, SKIP to ITEM 5. (If active ingredient is from a registered source (manufacturing-use product), generic data should be satisfied by registered source.) IF NO or if use not supported by registered source, generic data is necessary.		
e.	Data passed PR Notice 86-5 for formatting and MRID number assignment?		
f.	Public copy of Data Matrix provided? (PRN 98-5)		
5.	Certification with Respect to Citation of Data (EPA Form 8570-34): See 40 CFR 152.80-98 and PR Notice 98-5 [Note: If no data are required or submitted, form is not needed. This is often true for minor amendments.]		
a.	Did applicant check a Method of Support?		
b.	General Offer to Pay checked for Cite-all Method or Cite-all under Selective Method?		
c.	Is the form signed and dated?		
d.	Check form and Data Matrix; are Exclusive Use data cited from other sources?		
e.	IF YES , is the required authorization letter included in application?		
6.	Formulators Exemption (EPA Form 5870-27)		
a.	If registrant is using a registered source active ingredient in the formulation (manufacturing-use product), is form filled out completely and signed? NA <input type="checkbox"/>		

#	Check list Item	Yes	No
7.	Exclusive Use Notice Requirement Prior to Registration (Required per 40 CFR 152.116, separate from permission of an exclusive use data submitter to rely on exclusive use data) Is this an exclusive use active ingredient or mix of active ingredients (registered w/in last 10 yrs)? If YES, go to a) or b) below.		
a.	a) Has a notification of intent to register letter or email been sent to the exclusive use data submitter(s) at least 30 days before registration? (This notification is required for all methods of data support except when the exclusive use data submitter(s)' product is used to formulate and the formulator's exemption is claimed.)		
b.	Has exclusive use data submitter requested during 30 day period the applicants' list of data requirements and method of compliance?		
c.	Has registrant submitted certification from exclusive use data submitter that submitter is aware of the application and does not object to the registration?		
8.	Science Review completed? Comments:		
9.	Label(s) Review Date of Label Review:		
a.	Label(s) in conformance with current <i>Label Review Manual</i> and appropriate REDS.		
b.	Labeling statements and claims are supported by Acute Toxicity, Product Chemistry data (or acceptable waivers). Acceptable efficacy studies support public health pests claimed on label.		
c.	Nominal concentration of active ingredient shown in ingredients statement.		
d.	Viability included as sub-statement of Ingredient Statement (if live microbial, i.e., cfu/gram).		
e.	Storage and disposal instructions agree with container types listed on application form.		
f.	Unique Product Name for Same Company (Check OPPIN).		
g.	Does CSF list peanuts, tree nuts, milk, soybeans, eggs (including putrescent eggs), fish, crustacea, or wheat commodities? If YES , RAL must evaluate label use directions for compliance with 40 CFR 180.1071.		
h.	Does label bear "National Organic Program" (PR Notice 2003-1) or OMRI claims?		
	If YES, National Organic Program or OMRI claims approved by Chris Pfeifer? <input type="checkbox"/> NA		
i.	Labeling is acceptable. Corrections or changes are NOT necessary.		
j.	Does the label bear any (industrial) hemp, cannabis, or marijuana uses? <ul style="list-style-type: none"> If YES, have the registrant remove. Cannabis, Hemp and/or marijuana shall not be on any label Also look for "medicinal plants," "medical plants," "aromatic plants" or other like undefined terms on the label - these terms could cleverly allow applications to marijuana 		
k.	Are DERs attached?		
l.	Comments:		



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

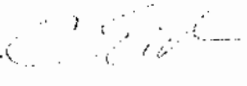
MEMORANDUM

DATE: 08/09/2018

SUBJECT: Science Review in support of registration of new end-use product, Cleanburn, containing 3% w/w Citronella oil as its active ingredient from unregistered source.

Decision Number:	534726
DP Number:	445771
EPA File Symbol Number:	33025-A
Chemical Class:	Biochemical
PC Code:	021901
CAS Number:	8000-29-1
Active Ingredients:	Citronella oil
Tolerance Exemptions:	Non-food
MRID Numbers:	505214-01 thru 505214-09

FROM: Clara Fuentes, PhD.
Entomologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

THRU: Catherine Eiden, Senior Advisor 
Risk Assessment Branch
Biopesticides & Pollution Prevention Division

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Lewis & Harrison Consultants in Government Affairs on behalf of Lamplight Farms, Inc. is requesting registration of a citronella-based mosquito repellent, Cleanburn, containing an unregistered source of active ingredient, Citronella oil, corresponding to the commercial variety "Java," extracted from *Cymbopogon winterianus*. The registrant is fulfilling product chemistry data requirements for the unregistered active ingredient in Cleanburn with data previously submitted for registration of similar product, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3). The source for the oil of citronella in Monarch 1101A and Clearburn is identical. The source of Citronella in Cleanburn remains unchanged from the time of the original registration of Monarch 1101A, and thus the registrant is bridging to MRIDs 486497-01, 486497-03, and 417857-03 respectively, for Manufacturing process of the active ingredient, Citronella oil, Discussion on formation of impurities; Enforcement analytical method that was employed for quantification of Citronella oil present in Monarch 1101A, and Physical/Chemical characteristics of Citronella oil Technical. The registrant references MRID 486497-02 in MRID 503898-02 for Preliminary Analysis of Citronella oil that was conducted for registration of Monarch 1101A.

Data on Product Identity & Composition, Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for End-Use product, Cleanburn, is provided in MRID 503898-01. Data on Physical/Chemical Characteristics of end-use product, Cleanburn, is provided in MRID 503898-03.

Tier I acute mammalian toxicity for the end-use product, Cleanburn, has been addressed with data in MRID 503898-05 for Acute oral; MRID 503898-06 for Acute eye irritation, and MRID 503898-07 for Acute dermal irritation.

Tier I acute mammalian toxicity for the active ingredient, Citronella oil, has been addressed by bridging to MRID 431794-01 for Acute oral; MRID 431671-01 for Acute dermal; MRID 431671-02 for acute inhalation; MRID 431671-03 for Acute eye irritation; MRID 431671-04 for Acute dermal irritation, and MRID 431671-05 for Skin sensitization. These toxicity studies correspond to Citronella oil, commercial variety "Java."

Tier I subchronic mammalian toxicity data, required for the active ingredient supplied from unregistered source, have been addressed with rationale in MRID 503898-11 for waiving further studies. MRID 503898-11 references mutagenicity data in MRIDs 417857-01 and 417857-02, and Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105) with references therein.

Non-target organisms' data requirements are addressed by bridging to data on Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*), A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*), and A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*) in MRIDs 417474-09, 417474-10, and MRID 417474-11, respectively.

Required data on Non-target plants and non-target insects, OCSPP 850.4000 and OCSPP 850.3020, respectively, is waived based on minimal exposure to plants and insects given the use pattern of the product, and the repellent effect of citronella oil on insects.

Lastly, product performance data is addressed by the cite all method. In addition, this submission includes copies of product label, CSF for basic and alternate formulations, dated 2/06/2018, and updated data matrix to address deficiencies identified by the Agency in an Agency's deficiency letter, dated on January 29, 2018.

BACKGROUND INFORMATION

The proposed product, Cleanburn, contains 3% w/w Citronella oil, corresponding to the commercial variety "Java," extracted from *Cymbopogon winterianus*. The source and percent concentration of the active ingredient, Citronella oil (Java variety), present in both, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3) and proposed product, Cleanburn, are identical. Thus, the registrant is bridging to product chemistry data submitted for registration of Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3) to satisfy product chemistry data requirements for Citronella oil in Cleanburn that is supplied by same unregistered supplier and present at the same concentration as in referenced product, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3). Cleanburn is a torch fuel formulation to be used outdoors as space repellent against mosquitoes. Label use directions instruct users to pour the content from the original container into vessel, canister or burner and wipe away any excess before lighting.

RECOMMENDATIONS AND CONCLUSIONS

Product chemistry: Acceptable.

- 1 The registrant has adequately addressed product chemistry data requirements for end-use product, Cleanburn, and its active ingredient, Citronella oil.

Studies classification for product chemistry:

Cited MRID 486497-01, Manufacturing process of the active ingredient, Citronella oil, and Discussion on formation of impurities is acceptable. (Refer to Confidential Appendix for details).

Submitted MRID 503898-02, bridging to MRID 486497-02 for Preliminary Analysis of Citronella oil, is acceptable. (Refer to Confidential Appendix for details).

Cited MRID 486497-03, is acceptable. Enforcement analytical method employed for quantification of Citronella oil present in Monarch 1101A, containing 3% w/w Citronella oil from same unregistered source as Cleanburn, is suitable for quantification of Citronella oil content in Cleanburn. Citronella oil is present at same concentration in both products, and it is supplied from same unregistered source.

MRID 503898-01, Product Identity & Composition, Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for End-Use product, Cleanburn, is acceptable.

Cited MRID 417857-03, Physical Chemical Characteristics of Citronella oil is acceptable.

MRID 503898-03, Physical/Chemical Characteristics of End-Use product, Cleanburn, is acceptable (Refer to Table 1).

Acute Mammalian Toxicity

Tier I Acute mammalian toxicity data for Citronella oil is acceptable. These data requirements have been adequately addressed by bridging to MRID 431794-01 for Acute oral; MRID 431671-01 for Acute dermal; MRID 431671-02 for acute inhalation; MRID 431671-03 for Acute eye irritation; MRID 431671-04 for Acute dermal irritation, and MRID 431671-05 for Skin sensitization. These cited studies correspond to Citronella oil, commercial variety "Java." Citronella oil is categorized under toxicity category III for acute oral, acute dermal toxicity, acute eye irritation, and acute dermal irritation, and under toxicity category IV for acute inhalation and skin sensitization.

Tier I Acute mammalian toxicity data for end-use product, Cleanburn, has been adequately addressed with data in MRID 503898-05 for acute oral; MRID 503898-06 for acute eye irritation, and MRID 503898-07 for acute dermal irritation.

MRIDs 503898-05, 503898-06 and 503898-07 for Acute oral, Acute Eye irritation, and Acute dermal irritation, respectively, are acceptable.

MRID 503898-11, Study waiver request for Acute dermal, Acute inhalation, and Skin sensitization is acceptable. The registrant's rationale is based on the composition of the formulation (Refer to Confidential Appendix for product composition), use pattern (not for intentional application to human skin), and low toxicity profile of Citronella oil (toxicity category III for acute dermal, and toxicity category IV for acute inhalation and skin sensitization).

MRIDs 505214-01 thru 505214-05 are acceptable. These MRIDs cite Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), with referenced MRID studies therein, in support for waiving Tier I subchronic toxicity studies.

MRID 505214-01 is acceptable. Waiver request for immunotoxicity studies is supported by referenced data in MRIDs 417857-01, and 417857-02. Data in these studies show that Citronella oil is not mutagenic.

MRID 505214-02, is acceptable. Rationale in support of waiving 90-day oral study is based on the use pattern of Cleanburn that will be used as torch fuel. Therefore, oral exposure is not anticipated.

MRID 505214-03 is acceptable. Rationale in support of waiving 90-day dermal study is based on the use pattern of Cleanburn that will be used as torch fuel. Therefore, intentional or prolonged exposure to the product from application to human skin is unlikely.

MRIDs 505214-04 and 505214-05, are acceptable. Request for waiving 90-day Inhalation and Developmental toxicity studies, respectively, is based on Reregistration Eligibility Decision for Oil of Citronella (CASE 3105). These data requirements have been waived in the Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), based on the low toxicity profile of Citronella oil (Commercial variety "Java," which is slightly toxic).

Non-target organisms:

MRID 417474-09, Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*) is acceptable.

Data on required Avian subacute dietary toxicity study, OSCPP 850.2200, is waived based on low acute oral toxicity. Oil of citronella is classified as Non-toxic to birds via the oral route. Furthermore, based on its use pattern, ingestion of the proposed product by birds is not expected.

MRID 417474-10, A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*) is acceptable. Oil of citronella has been classified as slightly toxic to fresh water fish.

MRID 41747411, A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*) is acceptable. Oil of citronella has been classified as slightly toxic to aquatic invertebrates.

Required data on Non-target plants and non-target insects, OCSPP 850.4000 and OCSPP 850.3020, respectively, are waived based on minimal exposure to plants and insects given the use pattern of the product, and the repellent effect of citronella oil on insects.

Product performance: Acceptable.

The registrant is resorting to the "cite all" method to satisfy product performance data requirement. The product Cleanburn is substantially similar in composition and use to the currently registered products Monarch 1101A, EPA Reg. No. 33025-3 and Cutter Insect Repellent Prometheus, EPA Reg. No. 121-85.

When Lamplight registered the product Monarch 1101A the "cite-all" method of data support was used for this registration referencing the Cutter Prometheus registration. The original application form and certification with respect to citation of data indicated that Cleanburn was substantially similar to Monarch 1101A. Lamplight is now claiming substantial similarity to Cutter Insect Repellent Prometheus, EPA Reg. No. 121-85. This is the same approach the registrant took for the registration of Monarch 1101A.

The products, Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85), Monarch 1101A (EPA Reg. No. 33025-3), or Cleanburn (EPA File Symbol No. 33025-A) are substantially similar 3% citronella torch fuel products.

Note to RAL

The use of “insects” in general as target pest is too broad and it should be removed from the label.

STUDIES SUMMARY

TABLE 1. Physical and Chemical Properties for Cleanburn (basic and alternate formulations)		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	N/A	N/A for EP
830.6303 Physical State	liquid	Visual observation
830.6304 Odor	N/A	N/A for EP
830.6313 Stability	N/A	N/A for EP
830.6315 Flammability	N/A	The product doesn't contain combustible liquids
830.6317 Storage Stability	65% geraniol after 14 days at 54°C ± 2°C.	Chromatographic analysis Geraniol peak area percent indicates percent geraniol in the product
830.6319 Miscibility	N/A	The product is not emulsible liquid to be diluted with petroleum solvents.
830.6320 Corrosion Characteristics	No signs of corrosion were noted on the commercial packing material, polyethylene terephthalate.	Visual inspection
830.7000 pH	5.37	pH meter
830.7100 Viscosity	2.5237 mm ² /s (cSt)	Ubbelohde viscometer
830.7300 Density/Relative Density/Bulk Density	0.8701 g/mL	CCL SOP 10.16 method

Data from MRID 503898-03

B. Acute Mammalian Toxicity

Table 2. Toxicological Profile of End-Use product, Cleanburn, Basic Formulation

MRID	Guideline	Test	Results LD ₅₀ /LC ₅₀	Toxicity Category
503898-05	870.1100	Acute Oral Toxicity	>5000 mg/kg	IV
503898-11	870.1200	Acute Dermal Toxicity	Waiver	Waiver
503898-11	870.1300	Acute Inhalation Toxicity	Waiver	Waiver
503898-06	870.2400	Primary Eye Irritation	Mildly irritating - free of irritation by 72 hours	III
503898-07	870.2500	Primary Dermal Irritation	Slightly irritating to skin	IV
503898-11	870.2600	Skin Sensitization	Waiver	Waiver

Table 3. Toxicological Profile of End-Use product, Cleanburn, Alternate Formulation

MRID	Guideline	Test	Results	Category
50389808	870.1100	Acute Oral Toxicity	>5000 mg/kg	IV
50389811	870.1200	Acute Dermal Toxicity	Waiver	Waiver
50389811	870.1300	Acute Inhalation Toxicity	Waiver	Waiver
50389809	870.2400	Primary Eye Irritation	Minimally irritating - free of irritation by 48 hours	III
50389810	870.2500	Primary Dermal Irritation	Slightly irritating to skin	IV
50389811	870.2600	Skin Sensitization	Waiver	Waiver

MRID 503898-11, Data waiver requests for Acute dermal, Acute inhalation, and Skin sensitization are based on the following rationale specific to each data requirement:

OCSP 870.1200 Acute Dermal Toxicity:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 2:

"2. *Required unless test material is corrosive to skin or has a pH between < 2 or 11.5 >.*" The pH of Cleanburn is 5.37.

In addition, under conditions of use, Cleanburn is not expected to result in dermal exposure.

OCSP 870.1300 Acute Inhalation Toxicity:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 3:

"3. Required when the product consists of, or under conditions of use would result in, a respirable material (e.g., gas, volatile substances, or aerosol particulate). . . ."

Concerning Test Note 3, Cleanburn is a liquid and does not consist of a respirable material, such as a gas, vapor or particulate.

OCSPP 870.2600 Skin Sensitization:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 2 & 4:

"2. Required unless test material is corrosive to skin or has a pH between < 2 or 11.5 >."

"4. Required if repeated contact to human skin is likely to occur under conditions of use"

Concerning Test Note 2, the pH of Cleanburn is 5.37.

Concerning Test Note 4, under conditions of use Cleanburn is not expected to result in repeated dermal exposure.

In addition, the battery of acute mammalian toxicity studies already conducted on Citronella oil show that Citronella oil is of low mammalian toxicity, classified under toxicity category III for acute oral, acute dermal, acute eye irritation, and acute dermal irritation, and under toxicity category IV for acute inhalation and skin sensitization.

Table 4. Toxicological Profile of Citronella oil

<u>Study Type/OCSPP Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID</u> (Java variety)
Acute Oral Toxicity/OCSPP 870.1100	> 4,860 mg/kg	III	431794-01
Acute Dermal Toxicity/OCSPP 870.1200	> 2,000 mg/kg	III	431671-01
Acute Inhalation Toxicity/OCSPP 870.1300	> 3.1 mg/L	IV	431671-02
Acute Eye Irritation/OCSPP 870.2400	Mild irritant	III	431671-03
Acute Dermal Irritation/OCSPP 870.2500	slightly irritant.	III	431671-04
Skin Sensitization/OCSPP 870.2600	Non- sensitizer	IV	431671-05
Hypersensitivity incidents	None reported		

The following Tier I Subchronic toxicity data are required for the active ingredient Citronella oil from an unregistered source: OCSPP 870.3100 90-day oral; OCSPP 870.3250 90-day dermal; OCSPP 90-day inhalation; OCSPP 870.3700 Prenatal development, and mutagenicity studies, OCSPP 870.5100 Bacterial reverse mutation test, and OCSPP 870.5300 / 870.5375 *In vitro* mammalian cell assay. The registrant is addressing these data requirements by bridging to data previously submitted for registration of Citronella oil technical (TGA1), and by providing the following rationale in support for waiving further testing:

According to the Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105), These data requirements were previously waived by the Agency for the following reasons:

1. The acute mammalian studies listed on Table 5, showed no significant adverse effects for various routes of exposure (Toxicity Category III for acute oral, dermal toxicity, acute eye irritation, and acute dermal irritation, and Toxicity Category IV for acute Inhalation and skin sensitization). (Refer to Table 5 for toxicological profile of Citronella oil).
2. The GRAS status of oil of citronella (21 CFR 182.2).
3. No report of hypersensitivity of adverse effects following oral and dermal exposure (which is currently accurate).
4. This rationale was used to develop and support an exemption under Section 25(b).

Specifically, the registrant has submitted MRIDs 505214-01 thru 505214-05 to address each Tier I subchronic toxicity data requirement individually:

MRID 505214-01, Waiver request for immunotoxicity.

The registrant is citing Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), with referenced MRID studies therein, in support for waiving additional immunotoxicity testing. According to the Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105), these data were previously waived by the Agency. Cited mutagenicity studies, Salmonella / mammalian microsome reverse mutation assay in MRIDs 417857-01, and *In vitro* Cytogenetic Assay, measuring chromosomal frequencies in Chinese hamster ovary cells in MRID 417857-02, show that Citronella oil is not mutagenic. No increase in the number of histidine revertants per plate with or without S9 (3300 µg/plate/+S9; 1,000 µg/plate/-S9, respectively) were reported in MRID 417857-01, and no chromosomal aberrations in Chinese hamster ovary with or without S9 (150 µg/plate/+S9; 75.5 µg/plate/-S9, respectively) were observed in MRID 417857-02 study.

MRID 505214-02, Waiver request for 90-day oral study is based on the following rationale: According to the regulations in 40 CFR §158.2050, a 90-day oral toxicity study is required if the use pattern of the active ingredient is likely to result in repeated oral exposure to humans. Cleanburn will be used as torch fuel. Therefore, it is not expected that there would be any oral exposure.

MRID 505214-03, Waiver request for 90-day dermal toxicity study is based on footnote #7 per 40 CFR §158.2050. According to the regulations in 40 CFR §158.2050, the data is required if the product is purposely applied to human skin. Cleanburn will be used as torch fuel. Therefore, it is not expected that there will be intentional or prolonged exposure to the product from application to human skin.

MRIDs 505214-04 and 505214-05, 90-day Inhalation and Developmental toxicity, respectively. These data requirements have been waived in the Reregistration Eligibility Decision for Oil of Citronella (CASE 3105) based on the following rationale:

1. The acute mammalian studies listed on Table 5, showed no significant adverse effects by various routes of exposure (Toxicity Category III for acute oral, acute dermal toxicity, acute eye irritation, and acute dermal irritation, and toxicity category IV for acute Inhalation and skin sensitization). (Refer to Table 4 for toxicological profile of Citronella oil).
2. The GRAS status of oil of citronella (21 CFR 182.2).
3. No report of hypersensitivity of adverse effects following oral and dermal exposure (which is currently accurate).
4. This rationale was used to develop and support an exemption under Section 25(b).
5. Immunotoxicity data in referenced studies, MRIDs 417857-01 and 417857-02 show that Citronella oil is not mutagenic.

C. Non-Target Organisms

MRID 417474-09, Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*).

The acute oral LD₅₀ value for Northern bobwhite quail exposed to oil of citronella as a single oral dosage was greater than 2250 mg/kg. The LOAEL was 2,250 mg/kg. The NOAEL was 1,350 mg/kg, based on the reduction in body weight for all birds at 2250 mg/kg. Based on these values, oil of citronella is classified as Non-toxic to birds via the oral route.

MRID 417474-10, A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*)

The LC₅₀ > 17.3 mg/L is based on nominal concentration of oil of citronella. Oil of citronella has been classified as slightly toxic to fresh water fish.

MRID 417474-11, A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*).

The EC₅₀ = 26.4 mg/L at 48 hours with 95% CL (13.0 mg – 36.0 mg oil of citronella). Based on these results, Oil of citronella has been classified as slightly toxic to aquatic invertebrates.

Data on required Avian dietary toxicity study, OSCPP 850.2200, is waived based on low acute oral toxicity. Oil of citronella is classified as Non-toxic to birds via the oral route. Furthermore, based on its use pattern, ingestion of the proposed product by birds is not expected

Data on Non-target plants and non-target insects, OCSP 850.4000 and 850.3020, respectively, have been waived based on minimal exposure to plants and insects given the use pattern of the product and the repellent effect of citronella oil on insects.

Product Performance: No efficacy study on substantially similar products has been found. Therefore, efficacy studies on file are for different products and substantially similar formulations are not suitable for characterizing performance of the Cleanburn product. Product performance data is required for the registration of Cleanburn with a claim of efficacy against mosquitoes.

cc: Clara Fuentes, RAL Menyon Adams, BPPD Chron File, IHAD/ARS FT, PY-S: 08/09/2018.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

January 29, 2018

CONTAINS CONFIDENTIAL BUSINESS INFORMATION

BY REGULAR MAIL AND EMAIL
RETURN RECEIPT REQUESTED

OPP Decision Number: 534726
EPA File Symbol: 33025-A
Pesticide Petition Number: N/A
Product Name: Cleanburn
EPA Receipt Date: October 06, 2017
EPA Company Number: 33025
Company Name: Lamplight Farms, Inc.

Georgia Anastasiou
Lamplight Farms, Inc
D/B/A Lewis & Harrison, LLC
122 C Street, NW Suite 505
Washington, DC 20001

Dear Ms. Anastasiou:

The U.S. Environmental Protection Agency (Agency or EPA) has completed its preliminary technical screening of your application pursuant to Section 33(1)(4)(B)(i)(II) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). The EPA has determined that your application has not passed the preliminary technical screening and therefore is subject to rejection if the application is not corrected.

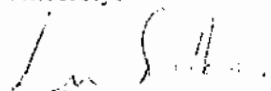
Specifically, you must provide the data and/or information described in the "Deficiencies" portion of the Confidential Appendix to this letter.

Page 2 of 2
EPA File Symbol No. 33025-A
OPP Decision No. 534726

In order for the review of your pesticide product to continue, you will need to correct your application to address the "Deficiencies" items listed in the Confidential Appendix within 10 business days of the date you received this letter. The EPA must receive your correction by the 10th business day. The EPA recommends sending your correction by email to the contact listed below to ensure it is received in a timely manner. If studies or confidential business information are being submitted by mail, a complete courtesy copy, minus confidential information, received by email by the deadline will be considered timely. If you cannot correct the application or do not respond within 10 business days, your application will be rejected. At this time, you could also choose to withdraw your application.

If you have questions concerning this letter, please contact Menyon Adams of my branch by telephone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,



Linda A. Hollis, Chief
Biochemical
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs

Enclosure

CONFIDENTIAL APPENDIX

Deficiencies Noted During the Technical Screen:

EPA File Symbol: 33025-A

Deficiencies:

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed
Subchronic Mammalian Toxicity Requirements per 40 CFR § 158.2050	Subchronic Toxicity data requirements for 90-day oral (OCSP 870.3100), 90-day dermal (OCSP 870.3250), 90-day inhalation (OCSP 870.3465), Prenatal development (OCSP 870.3700), and <i>In vitro</i> mammalian cell assay (OCSP 870.5300/ 870.5375) were addressed by making reference to pages 28 thru 29 of EPA Citronella Registration Eligibility Document (RED).	To satisfy the subchronic data requirements, your submission, specifically, data matrix made reference to pages 28 thru 29 of EPA Citronella RED. If you wish to cite to an agency document that summarizes the agency's safety findings on a particular chemical or class of compounds, then you must provide an argument as to why the EPA's findings are relative to the data requirement for the substance for which you seek registration. Discuss why the findings remain relevant and discuss any recent scientific findings/developments/changes (if any) and how those changes are not expected to affect and/ or change what the agency concluded when the agency's safety finding was made.	All data requirements must be submitted in separate data volumes addressing each data requirement separately. Furthermore, you must satisfy the 90-day oral (OCSP 870.3100), 90-day dermal (OCSP 870.3250), 90-day inhalation (OCSP 870.3465), Prenatal development (OCSP 870.3700), and <i>In vitro</i> mammalian cell assay (OCSP 870.5300/ 870.5375) data requirements with one of the following options: A. Conduct and submit a guideline study to fulfill the data requirement(s) or; B. Request a waiver for the data requirement(s). (Note: A waiver means that you are requesting to NOT address the data requirement because the data requirement is not applicable because of x,y,z reasons. You MUST state the reason(s) why

<p>Non-target organisms data requirements 40 CFR § 158.2060</p>	<p>Non-target organisms data requirements for Avian Dietary Toxicity (OCSP 850.2200), Seedling emergence (OCSP 850.4100), Vegetative vigor (OCSP 850.4150), Non-target insect (OCSP 880.4350) were addressed by making reference to pages 27 thru 28 of EPA Citronella RED.</p>	<p>To satisfy the non-target organisms data requirements, your submission, specifically, data matrix made reference to pages 28 thru 29 of EPA Citronella RED. If you wish to cite to an agency document that summarizes the agency's safety findings on a particular chemical or class of compounds, then you must provide an argument as to why the EPA's findings are relative to the data requirement for the substance for</p>	<p>the requirement is not applicable) or: C. Address the data requirement(s) by way of a citation(s) to a study(s) from the open scientific literature. The study should be conducted using either the test substance or a substance that is chemically and structurally similar to the test substance. In addition, you must provide a valid scientific rationale as to the findings of the study and a bridging argument. The bridging argument is a rationale that provides the reasons why the study can be bridged to satisfy the data requirement for the test substance. A copy of the published literature upon which you are relying must be provided. All data requirements must be submitted in separate data volumes addressing each data requirement separately. Furthermore, you must satisfy the Avian Dietary Toxicity (OCSP 850.2200), Seedling emergence (OCSP 850.4100), Vegetative vigor (OCSP 850.4150), Non-target insect (OCSP 880.4350) data requirements with one of the following options:</p>
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which you seek registration.

Discuss why the findings remain relevant and discuss any recent scientific

findings/developments; changes (if any) and how those changes are not expected to affect and/ or change what the agency concluded when the agency's safety finding was made.

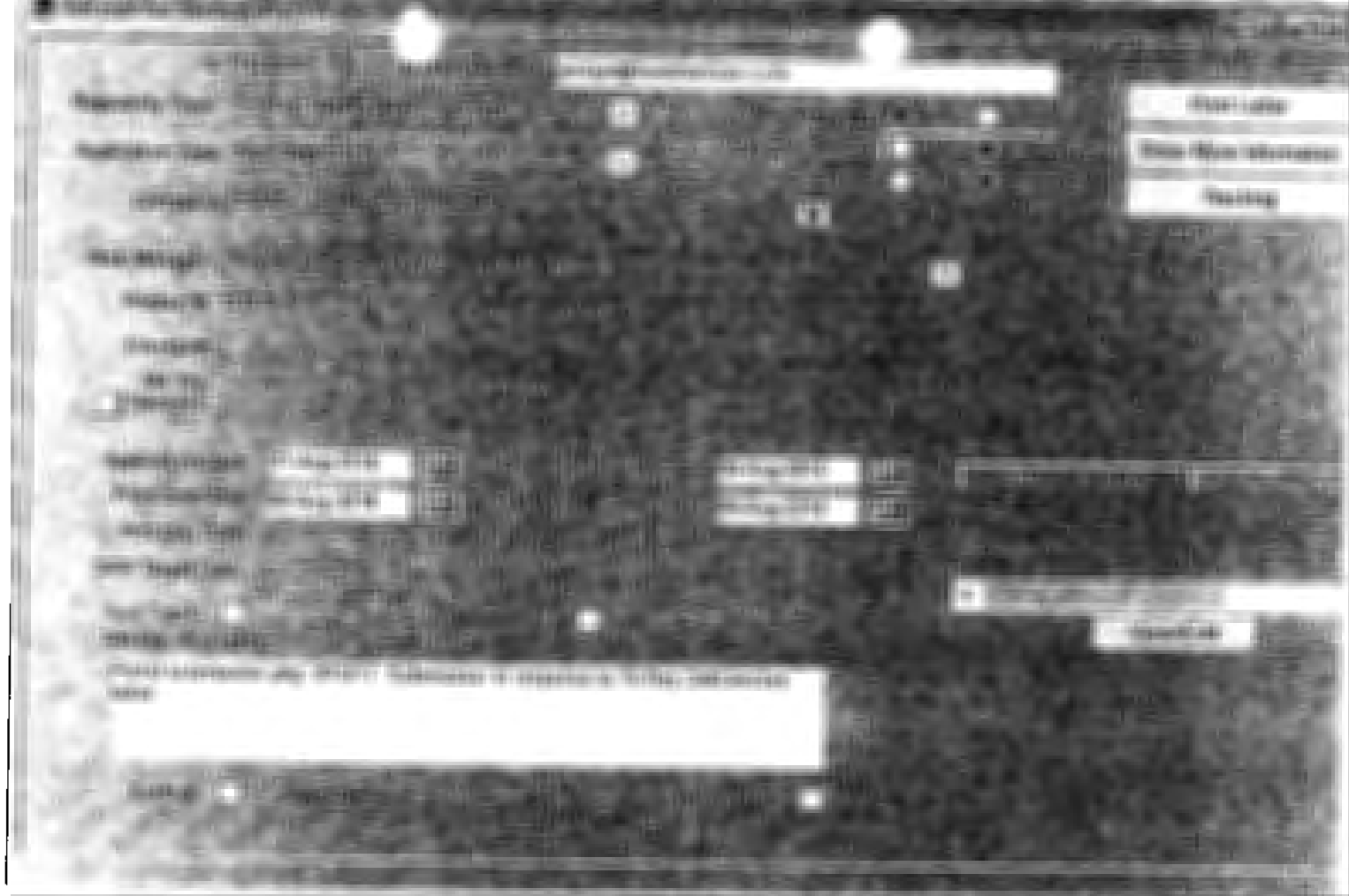
A. Conduct and submit a guideline study to fulfill the data requirement(s) or:

B. Request a waiver for the data requirement(s). (Note: A waiver means that you are requesting to NOT address the data requirement because the data requirement is not applicable because of x,y,z reasons. You MUST state the reason(s) why the requirement is not applicable) or:


C. Address the data requirement(s) by way of a citation(s) to a study(s) from the open scientific literature. The study should be conducted using either the test substance or a substance that is chemically and structurally similar to the test substance. In addition, you must provide a valid scientific rationale as to the findings of the study and a bridging argument. The bridging argument is a rationale that provides the reasons why the study can be bridged to satisfy the data requirement for the test substance. A copy of the published literature upon which you are relying must be provided.

Shortcomings

Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed
Active ingredient name and concentration discrepancies on label and Confidential Statement of Formula (CSF).	Product label and CSF dated September 11, 2017.	The active ingredient name on product label is "Oil of Citronella." The active ingredient is listed on the CSF as Citronella oil. Furthermore, the concentration of active ingredient listed on product label is 3%. The concentration of active ingredient listed on the CSF is 3.0%	The CSF and label must be amended regarding the name and concentration of active ingredient. Name and concentration of active ingredient must be consistent between label and CSF.



Page 1 of 1

	EPA United States Environmental Protection Agency Washington, DC 20460	<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
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Application for Pesticide - Section I

1. Company/Product Number 33025-A	2. EPA Product Manager Linda A Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) CLEANBURN	PM# BPPD	
5. Name and Address of Applicant (Include ZIP Code) Lamplight Farms, Inc. c/o Lewis & Harrison, LLC 2461 S. Clark St., Suite 710 Arlington, VA 22202 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>Cutter Insect Repellent Prometheus</u> Product Name: <u>121-85</u>

Section - II

<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below
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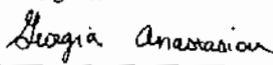
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)

Response to 75 Day Deficiencies Letter dated June 18, 2018

Section - III

1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2- 128 fl. oz.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			

Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)		
Name Georgia Anastasiou, Lewis & Harrison, LLC	Title Agent	Telephone No. (Include Area Code) 202-393-3903 x. 119
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature 	3. Title Agent	
4. Typed Name Georgia Anastasiou	5. Date 8/1/2018	

LEWIS & HARRISON

Consultants in Government Affairs

2461 S. Clark St., Suite 710
Arlington, VA 22202

telephone 202.393.3903
fax 202.393.3906

August 1, 2018

E-Submission

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Linda A. Hollis
Chief, Biopesticides and Pollution Prevention Division

SUBJECT: Lamplight Farms, Inc.
Cleanburn (EPA File Symbol 33025-A)
Response to 75 Day Deficiencies Letter dated June 18, 2018

Dear Ms. Hollis:

On behalf of Lamplight Farms, Inc. ("Lamplight"), I am responding to the 75 Day Deficiencies Letter for Product Performance and Product Chemistry Data dated June 18, 2018 (attached) for the product Cleanburn, EPA File Symbol 33025-A. Please see below for the response to each deficiency.

Deficiency #1

The cited MRID's for the physical and chemical data requirements below did not include the methods that were used. Methods used in determining the following physical/chemical characteristic for Citronella must be provided. OCSPP 830.6313 Stability; OCSPP 830.6315 Flammability; OCSPP 830.6317 Storage Stability; OCSPP 830.6320 Corrosion characteristics; OCSPP 830.7300 Density/Relative Density/Bulk Density, and OCSPP 830.7950 Vapor pressure.

Response #1

Lamplight cited specific studies that were listed in the Oil of Citronella Reregistration Legibility Decision (RED) to fulfill product chemistry generic data requirements. This same approach was accepted in the past by the Agency for the substantially similar product Monarch 1101A (EPA Reg. No. 33025-3); however to satisfy this request, the generic data matrix has been updated. Lamplight is using the selective method, "cite-all" option to meet these data requirements. This approach should fulfill any generic product chemistry data requirements

Deficiency #2

The cited MRID's for the physical and chemical data requirements but did not include numerical values and methods that were used. Measurable numerical values and method of determinations for these physical/chemical characteristics of Citronella oil must be provided. OCSPP 830.700 pH; OCSPP 830.7050 UV/Visible light absorption; OCSPP 830.7100 Boiling point; OCSPP 830.7550, 830.7560, 830.7570 Partition Coefficient (n-Octanol/water), and OCSPP 830.840 Water solubility.

Response #2

Please see Response #1.

Deficiency #3

The manufacturing process of the end-use product, Cleanburn, is described in MRID 503898-01. However, the quantity of each ingredient used in the formulation is not reported and the packaging and packaging material is not described. You must report the quantity of each ingredient used in the formulation during production process, and described packaging and packaging material.

Response #3

Lamplight has updated the manufacturing process to include the requested information. Enclosed please find the updated manufacturing process (MRID 50648401).

Deficiency #4

Product performance data must be submitted and, specifically, should support all claims against public health pests appearing on the product label. You chose the "cite all" method to satisfy product performance data requirement, however, no efficacy study has been found suitable for characterizing efficacy of the proposed product against mosquitos in the USA. Specifically, product performance data is needed for determination of space of effective repellency cover by one canister, how many burning canisters are needed for effective coverage of a given space, and how to place canister for optimal coverage of a given space.

Response #4

The product Cleanburn is substantially similar in composition and use to the currently registered products Monarch 1101A, EPA Reg. No. 33025-3 and Cutter Insect Repellent Prometheus, EPA Reg. No. 121-85. When Lamplight registered the product Monarch 1101A the "cite-all" method of data support was used for this registration referencing the Cutter Prometheus registration. The original application form and certification with respect to citation of data indicated that Cleanburn was substantially similar to Monarch 1101A. To eliminate any confusion, Lamplight is now claiming substantial similarity to Cutter Insect Repellent Prometheus, EPA Reg. No. 121-85. This is the same approach Lamplight took for the registration of Monarch 1101A.

If the Agency has now determined that it has inadequate efficacy data in its files to support registration of these substantially similar 3% citronella torch fuels (Cutter Insect Repellent Prometheus, EPA Reg. No. 121-85, Monarch 1101A, EPA Reg. No. 33025-3, or Cleanburn, EPA File Symbol No. 33025-A) then it should issue a DCI for the needed data pursuant to FIFRA §3(c)(2)(B). Further, pending submission of the needed efficacy data, EPA should conditionally register Cleanburn under FIFRA §3(c)(7)(A).

Deficiency #5

You must revise the propose product label to include the following use instructions: • Do not use in windy conditions. • Do not tip torch as fuel can spill and cause fire. • Do no use gasoline or other combustible or flammable fluids. • Do not place torch under covered shelter. • Do no please torch near pedestrian traffic, wood, clothing or dry vegetation. • Adjust wick height no higher than ¾ inches. • Keep clothing, hair and face away from flame. •To extinguish flame, please snuffer cap completely over wick until flame is extinguished.

Response #5

These use instructions do not apply to the torch fuel, but are associated with a torch. The fuel will not be sold with a torch; therefore these instructions are not applicable to the product and would be confusing to the customer. Furthermore, these statements were not required for other substantially similar torch fuel products such as Monarch 1101A, EPA Reg. No. 33025-3 and Cutter Insect Repellent Prometheus, EPA Reg. No. 121-85. To address concerns when used with a torch the following language has been added to the directions for use "Follow all torch manufactures instructions for use".

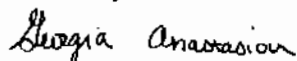
In addition, please be aware that we also added the additional brand name "TIKI Brand Paradise in Your Backyard Clean Burn BiteFighter Torch Fuel" to the label.

In support of this of this response, enclosed please find the following documents:

- 1) Updated Application;
- 2) Updated Product Label;
- 3) Updated End Use Data Matrix (both Public and Agency copies);
- 4) Updated Generic Data Matrix (both Public and Agency copies);
- 5) Transmittal Document; and,
- 6) Updated manufacturing use data.

If you have any questions about this submission, please contact me at (202) 393-3903 ext. 119 or by email at georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)
Luke Zeitler (Lamplight)

EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: **August 1, 2018**
STUDY SUBMITTER: **Lamplight Farms**
4900 North Lilly Road
Menomonee Falls, WI 53051
PRODUCT: **CLEANBURN**
EPA REG. NO.: **33025-A**
REGULATORY ACTION: **PRIA Code B673**

STUDIES SUBMITTED:

MRID: 50648401 CLEANBURN: Manufacturing Use Process (August 1, 2018) by Georgia Anastasiou, Lewis & Harrison; 5 pages, including 4 page confidential appendix.

COMPANY CONTACT: **Georgia Anastasiou**
Lewis & Harrison, LLC
123 C Street NW, Suite 505
Washington, DC 20001
(202) 393-3903 x119
georgia@lewisharrison.com



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DATA MATRIX

Date August 1, 2018		EPA Reg. No./File Symbol 33025-A		Page 1 of 2	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product Cleanburn			
Ingredient(s): Citronella Oil (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note

PRODUCT CHEMISTRY

880.1100	Product Identity & Composition	50389801	Lamplight Farms Inc. (33025)	OWN	
880.1200	Description of starting materials, production & formulation process used to produce product	50648401	Lamplight Farms Inc. (33025)	OWN	
880.1400	Discussion of formation of impurities	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1700	Preliminary Analysis	50389802	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	
830.1750	Certified Limits	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1800	Enforcement Analytical Method	50389801	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	
Physical/Chemical Properties					
830.6302	Color	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6303	Physical State	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6304	Odor	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6315	Flammability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6319	Miscibility	N/A			Footnote 1
830.6317	Storage stability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6320	Corrosion characteristics	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7000	pH	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7100	Viscosity	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7300	Density/Relative Density	50389803	Lamplight Farms Inc. (33025)	OWN	

TOXICOLOGY

	Acute Toxicity Summary	50389804	Lamplight Farms Inc. (33025)	OWN	
870.1100	Acute Oral Toxicity	50389805	Lamplight Farms Inc. (33025)	OWN	
		50389808	Lamplight Farms Inc. (33025)	OWN	
870.1200	Acute Dermal Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
870.1300	Acute Inhalation Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver

Signature: <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date August 1, 2018
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DATA MATRIX

Date August 1, 2018			EPA Reg. No./File Symbol 33025-A		Page 2 of
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051			Product Cleanburn		
Ingredient(s): Citronella Oil (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	50389806 50389809	Lamplight Farms Inc. (33025) Lamplight Farms Inc. (33025)	OWN OWN	
870.2500	Primary Dermal Irritation	50389807 50389810	Lamplight Farms Inc. (33025) Lamplight Farms Inc. (33025)	OWN OWN	
870.2600	Skin Sensitization	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
EFFICACY					
	Product Performance	CITE-ALL	See-Attached List	PAY	

FOOTNOTES

1. A miscibility study is not applicable since the subject product is not diluted with petroleum distillates.

Signature : <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date August 1, 2018
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DATA MATRIX

Date August 1, 2018	EPA Reg. No./File Symbol 33025-A	Page 1 of 2
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051	Product Cleanburn	

Ingredient(s): **Citronella Oil (PC code 021901)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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PRODUCT CHEMISTRY

880.1100	Product Identity & Composition	50389801	Lamplight Farms Inc. (33025)	OWN	
880.1200	Description of starting materials, production & formulation process used to produce product	50648401	Lamplight Farms Inc. (33025)	OWN	
880.1400	Discussion of formation of impurities	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1700	Preliminary Analysis	50389802	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	
830.1750	Certified Limits	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1800	Enforcement Analytical Method	50389801	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	
Physical/Chemical Properties					
830.6302	Color	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6303	Physical State	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6304	Odor	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6315	Flammability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6319	Miscibility	N/A			Footnote 1
830.6317	Storage stability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6320	Corrosion characteristics	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7000	pH	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7100	Viscosity	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7300	Density/Relative Density	50389803	Lamplight Farms Inc. (33025)	OWN	

TOXICOLOGY

	Acute Toxicity Summary	50389804	Lamplight Farms Inc. (33025)	OWN	
870.1100	Acute Oral Toxicity	50389805	Lamplight Farms Inc. (33025)	OWN	
		50389808	Lamplight Farms Inc. (33025)	OWN	
870.1200	Acute Dermal Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
870.1300	Acute Inhalation Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver

Signature: <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date August 1, 2018
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DATA MATRIX

Date August 1, 2018		EPA Reg. No./File Symbol 33025-A		Page 2 of 2	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product Cleanburn			
Ingredient(s): Citronella Oil (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	50389806	Lamplight Farms Inc. (33025)	OWN	
		50389809	Lamplight Farms Inc. (33025)	OWN	
870.2500	Primary Dermal Irritation	50389807	Lamplight Farms Inc. (33025)	OWN	
		50389810	Lamplight Farms Inc. (33025)	OWN	
870.2600	Skin Sensitization	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
EFFICACY					
	Product Performance	CITE-ALL	See-Attached List	PAY	

FOOTNOTES

1. A miscibility study is not applicable since the subject product is not diluted with petroleum distillates.

Signature : <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date August 1, 2018
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59 COOPERS ANIMAL HEALTH INC SPECTRUM, A DIV OF UNITED 121 INDUSTRIES CORP	REGULATORY AFFAIRS PO BOX 142642	421 EAST HAWLEY ST	MUNDELEIN ST LOUIS	IL MO	60060 63114064 2 53956131
134 HACCO, INC.		110 HOPKINS DRIVE	RANDOLPH	WI	6
270 FARNAM COMPANIES, INC.		1501 E. WOODFIELD ROAD., SUITE 200 WEST	SCHAUMBURG	IL	60173
9201 CANDLE CORP OF AMERICA		999 EAST TOUHY AVE, SUITE 450	DES PLAINS	IL	60018
65233 PRIMAVERA LABORATORIES, INC	GARVEY, SCHUBERT & BARER	1000 POTOMAC STREET, NW, 5TH FLOOR	WASHINGTON	DC	20007
66607 SPRAY DRIFT TASK FORCE MP-ESPREE, LLC D/B/A ESPREE ANIMAL 66963 PRODUCTS, INC.	ALDRIDGE LLP REGULATORY CONSULTANTS, INC.	1900 K STREET, NW	WASHINGTON	DC	20006
73878 COMPANY, LLC	GROUP INC.	201 W. VAN BUREN STREET	COLUMBIA CITY,	IN	46725
74888 (REJV)	CSPA/PIR	1101 17TH ST NW, SUITE 500	WASHINGTON	DC	20036
80657 THE COMPANION GROUP	REGWEST COMPANY, LLC	300	WASHINGTON	DC	20006
82868 ROSEMONT VENTURES, INC.		8203 WEST 20TH STREET, SUITE A	GREELEY	CO	80634469 6
84676 SPRING TRADING COMPANY		ONE GATEWAY CENTER, SUITE 409	NEWTON	MA	02458
86870 BEAT IT LLC		203 DOGWOOD TRAIL	MAGNOLIA	TX	77354
		11 SE 2ND AVENUE	GAINESVILLE	FL	32601



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DATA MATRIX FOR ACTIVE INGREDIENT

Date August 1, 2018		EPA Reg. No./File Symbol 33025-A		Page 1 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
880.1100	Product Identity & Composition	48649701	Lamplight Farms (33025)	OWN	
880.1200	Description of starting materials, production & formulation process used to produce product	48649701	Lamplight Farms (33025)	OWN	
880.1400	Discussion of formation of impurities	48649701	Lamplight Farms (33025)	OWN	
830.1700	Preliminary analysis	48649702	Lamplight Farms (33025)	OWN	
830.1750	Certified Limits	cite-all	See attachment for data submitters	PAY	
830.1800	Enforcement analytical method	48649702	Lamplight Farms (33025)	OWN	
		cite-all	See attachment for data submitters	PAY	
830.6302	Color	cite-all	See attachment for data submitters	PAY	
830.6303	Physical State	cite-all	See attachment for data submitters	PAY	
830.6304	Odor	cite-all	See attachment for data submitters	PAY	
830.6313	Stability	cite-all	See attachment for data submitters	PAY	
830.6315	Flammability	cite-all	See attachment for data submitters	PAY	
830.6317	Storage Stability	cite-all	See attachment for data submitters	PAY	
830.6319	Miscibility	cite-all	See attachment for data submitters	PAY	
830.6320	Corrosion Characteristics	cite-all	See attachment for data submitters	PAY	
830.7000	pH	cite-all	See attachment for data submitters	PAY	
830.7050	UV/Visible light absorption	cite-all	See attachment for data submitters	PAY	
830.7100	Viscosity	cite-all	See attachment for data submitters	PAY	
830.7200	Melting point	cite-all	See attachment for data submitters	PAY	
830.7220	Boiling point	cite-all	See attachment for data submitters	PAY	
830.7300	Density	cite-all	See attachment for data submitters	PAY	
830.7520	Particle Size	N/A			(2)
830.7550-830.7570	Partition coefficient	cite-all	See attachment for data submitters	PAY	
830.7840	Water solubility	cite-all	See attachment for data submitters	PAY	

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date August 1, 2018
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DATA MATRIX FOR ACTIVE INGREDIENT

Date August 1, 2018		EPA Reg. No./File Symbol 33025-A		Page 2 of 2	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
830.7950	Vapor Pressure	cite-all	See attachment for data submitters	PAY	(1)
TOXICOLOGY					
870.1100	Acute Oral Toxicity	41747402 43179401	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.1200	Acute Dermal Toxicity	41747403 43167101	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.1300	Acute Inhalation Toxicity	41747404 43167102	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.2400	Primary Eye Irritation	41747405 43167103	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.2500	Primary Dermal Irritation	41747406 43167104	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.2600	Dermal Sensitization	41747407 43167105	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
	Hypersensitivity				Not Applicable
870.5385/870.5895	Microbial mutagenicity	41786701 41785702 41747408	Citronella Joint Venture (67736) Citronella Joint Venture (67736) Candle Corp (009201)	OLD OLD OLD	(1)
870.3550	Immunotoxicity	50521401	Lamplight Farms (33025)		
870.3100	90-Day oral toxicity	50521402	Lamplight Farms (33025)		
870.3250	90-Day dermal toxicity	50521403	Lamplight Farms (33025)		
870.3465	90-Day inhalation toxicity	50521404	Lamplight Farms (33025)		
870.3700	Prenatal Development	50521405	Lamplight Farms (33025)		

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date August 1, 2018
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DATA MATRIX

Date August 1, 2018	EPA Reg. No./File Symbol 33025-A	Page 1 c
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051	Product Cleanburn	

Ingredient(s): **Citronella Oil (PC code 021901)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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PRODUCT CHEMISTRY

880.1100	Product Identity & Composition	50389801	Lamplight Farms Inc. (33025)	OWN	
880.1200	Description of starting materials, production & formulation process used to produce product	50648401	Lamplight Farms Inc. (33025)	OWN	
880.1400	Discussion of formation of impurities	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1700	Preliminary Analysis	50389802	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	
830.1750	Certified Limits	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1800	Enforcement Analytical Method	50389801	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	

Physical/Chemical Properties

830.6302	Color	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6303	Physical State	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6304	Odor	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6315	Flammability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6319	Miscibility	N/A			Footnote
830.6317	Storage stability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6320	Corrosion characteristics	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7000	pH	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7100	Viscosity	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7300	Density/Relative Density	50389803	Lamplight Farms Inc. (33025)	OWN	

TOXICOLOGY

	Acute Toxicity Summary	50389804	Lamplight Farms Inc. (33025)	OWN	
870.1100	Acute Oral Toxicity	50389805	Lamplight Farms Inc. (33025)	OWN	
		50389808	Lamplight Farms Inc. (33025)	OWN	
870.1200	Acute Dermal Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
870.1300	Acute Inhalation Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver

Signature :

Georgia Anastasiou

Name and Title:

Georgia Anastasiou Agent for Lamplight Farms, Inc

Date

August 1, 2



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DATA MATRIX FOR ACTIVE INGREDIENT

Date August 1, 2018		EPA Reg. No./File Symbol 33025-A		Page 3 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ECOLOGICAL EFFECTS					
850.2100	Acute Avian Oral	41747409	Candle Corp (009201)	OLD	(1)
850.2200	Avian Dietary Toxicity	50521406	Lamplight Farms (33025)	-	
154B-8	Fish toxicity	41747410	Candle Corp (009201)	OLD	(1)
154B-9	Invertebrate Toxicity	41747411	Candle Corp (009201)	OLD	(1)
850.4100	Seedling emergence	50521407	Lamplight Farms (33025)		
850.4250	Vegetative vigor	50521408	Lamplight Farms (33025)		
880.4350	Nontarget insects	50521409	Lamplight Farms (33025)	-	
ENVIRONMENTAL FATE					
					Non-Applicable

FOOTNOTES

1. Per pages 27-28 of the Oil of Citronella RED, these generic data requirements have been fulfilled.
2. The dissociation constant data requirement is not applicable since citronella does not have any dissociable groups.

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date August 1, 2018
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DATA MATRIX

Date August 1, 2018		EPA Reg. No./File Symbol 33025-A		Page 2 of 2	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product Cleanburn			
Ingredient(s): Citronella Oil (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	50389806 50389809	Lamplight Farms Inc. (33025) Lamplight Farms Inc. (33025)	OWN OWN	
870.2500	Primary Dermal Irritation	50389807 50389810	Lamplight Farms Inc. (33025) Lamplight Farms Inc. (33025)	OWN OWN	
870.2600	Skin Sensitization	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
EFFICACY					
	Product Performance	CITE-ALL	See-Attached List	PAY	

FOOTNOTES

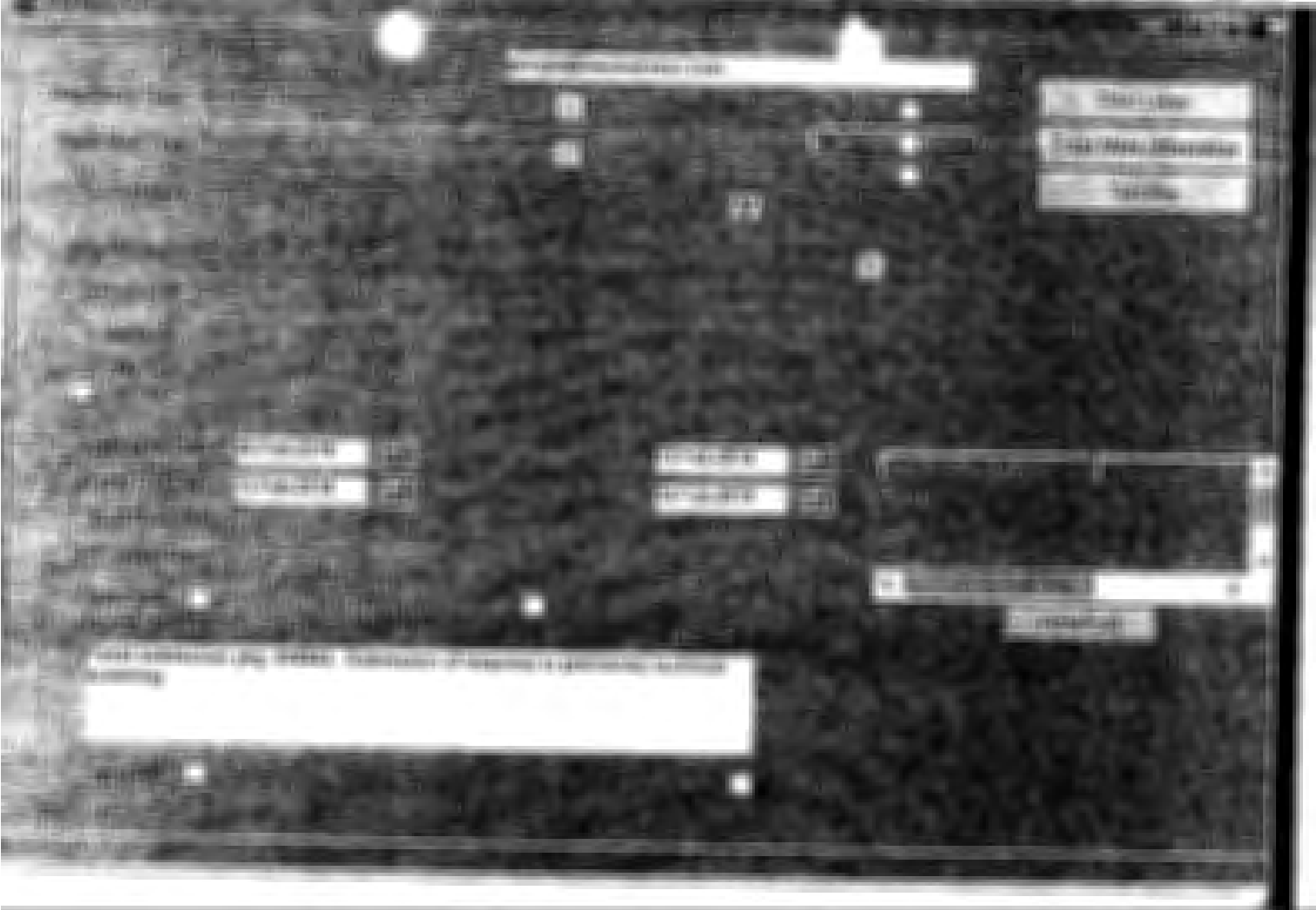
1. A miscibility study is not applicable since the subject product is not diluted with petroleum distillates.


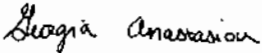
Signature : <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date August 1, 2018
--	--	------------------------

Citronella Oil - Data Submitters July 2, 2018

69

59 COOPERS ANIMAL HEALTH INC	REGULATORY AFFAIRS	421 EAST HAWLEY ST	MUNDELEIN	IL	60060
SPECTRUM, A DIV OF UNITED					63114064
121 INDUSTRIES CORP	PO BOX 142642		ST LOUIS	MO	2
					53956131
134 HACCO, INC.		110 HOPKINS DRIVE	RANDOLPH	WI	6
		1501 E. WOODFIELD ROAD.,			
270 FARNAM COMPANIES, INC.		SUITE 200 WEST	SCHAUMBURG	IL	60173
		999 EAST TOUHY AVE, SUITE			
9201 CANDLE CORP OF AMERICA		450	DES PLAINS	IL	60018
	GARVEY, SCHUBERT &	1000 POTOMAC STREET,			
65233 PRIMAVERA LABORATORIES, INC	BARER	NW, 5TH FLOOR	WASHINGTON	DC	20007
66607 SPRAY DRIFT TASK FORCE	ALDRIDGE LLP	1900 K STREET, NW	WASHINGTON	DC	20006
MP-ESPREE, LLC D/B/A ESPREE ANIMAL	REGULATORY				
66963 PRODUCTS, INC.	CONSULTANTS, INC.	201 W. VAN BUREN STREET	COLUMBIA CITY, IN		46725
73878 COMPANY,LLC	GROUP INC.	1101 17TH ST NW, SUITE 500	WASHINGTON	DC	20036
74888 (REJV)	CSPA/PIR	300	WASHINGTON	DC	20006
	REGWEST COMPANY,	8203 WEST 20TH STREET,			80634469
80657 THE COMPANION GROUP	LLC	SUITE A	GREELEY	CO	6
		ONE GATEWAY CENTER,			
82868 ROSEMONT VENTURES, INC.		SUITE 409	NEWTON	MA	02458
84676 SPRING TRADING COMPANY		203 DOGWOOD TRAIL	MAGNOLIA	TX	77354
86870 BEAT IT LLC		11 SE 2ND AVENUE	GAINESVILLE	FL	32601



 EPA United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 33025-A		2. EPA Product Manager Linda A Hollis	
4. Company/Product (Name) CLEANBURN		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Lamplight Farms, Inc. c/o Lewis & Harrison, LLC 122 C ST. NW, Suite 505 Washington, DC 20001		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>Tiki Insect Repellent Monarch 1101A</u> Product Name: <u>33025-3</u>	
<input type="checkbox"/> Check if this is a new address			
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.)			
Response to Preliminary Technical Screening Letter			
Section - III			
1. Material This Product Will Be Packaged In:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 2- 128 fl. oz.	
		5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product		<input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled	
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Georgia Anastasiou, Lewis & Harrison, LLC, 122 C Street NW, Ste. 505, Washington, DC 20001		Title Agent	Telephone No. (Include Area Code) 202-393-3903 x. 119
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Georgia Anastasiou		5. Date 2/6/2018	

EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: February 6, 2018
STUDY SUBMITTER: Lamplight Farms
4900 North Lilly Road
Menomonee Falls, WI 53051
PRODUCT: CLEANBURN
EPA REG. NO.: 33025-A
REGULATORY ACTION: PRIA Code B673

STUDIES SUBMITTED:

MRID: 50521401 CLEANBURN: Discussion of Waiver Request for Immunotoxicity
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521402 CLEANBURN: Discussion of Waiver Request for 90-Day Oral Toxicity
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521403 CLEANBURN: Discussion of Waiver Request for 90-Day Dermal Toxicity
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521404 CLEANBURN: Discussion of Waiver Request for 90-Day Inhalation Toxicity
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521405 CLEANBURN: Discussion of Waiver Request for Prenatal Development
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521406 CLEANBURN: Discussion of Waiver Request for Avian Dietary Toxicity
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521407 CLEANBURN: Discussion of Waiver Request for Seedling Emergence
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521408 CLEANBURN: Discussion of Waiver Request for Vegetative vigor
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50521409 CLEANBURN: Discussion of Waiver Request for Nontarget Insects
(February 6, 2018) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

COMPANY CONTACT: Georgia Anastasiou
Lewis & Harrison, LLC
123 C Street NW, Suite 505
Washington, DC 20001
(202) 393-3903 x119
georgia@lewisharrison.com

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001
telephone 202.393.3903
fax 202.393.3906

February 6, 2018

E-Submission

Document Processing Desk
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Linda A. Hollis
Chief, Biopesticides and Pollution Prevention Division

SUBJECT: Lamplight Farms, Inc.
CLEANBURN (EPA File Symbol 33025-A)
Response to Preliminary Technical Screening Letter

Dear Ms. Hollis:

On behalf of Lamplight Farms, Inc., I am responding to the Preliminary Technical Screening letter dated January 29, 2018 (attached) for the product CLEANBURN, EPA File Symbol 33025-A. Please see details below for the response to each deficiency:

Deficiency	Response
90-day oral data (870.3100)	Data waiver enclosed (MRID 50521401).
90-day dermal data (870.3250)	Data waiver enclosed (MRID 50521402).
90-day inhalation data (870.3465)	Data waiver enclosed (MRID 50521403).
Prenatal development (870.3700)	Data waiver enclosed (MRID 50521404).
In vitro mammalian cell assay (870.5300/870.5375)	The data citations for this requirement were listed in the original submission. I believe this request may be a typo and the immunotoxicity data requirement should have been listed since it was handled the same way as the other deficient data requirements. Therefore I have included a waiver request for the immunotoxicity data requirement (880.3550) instead (MRID 50521405).
Avian Dietary Toxicity (850.2200)	Data waiver enclosed (MRID 50521406).
Seedling emergence (850.4100)	Data waiver enclosed (MRID 50521407).
Vegetative vigor (850.4150)	The OPPTS guideline I believe should be 850.4250. The data waiver for the requirement Vegetative vigor (850.4250) is enclosed (MRID 50521408).
Non-target insects (880.4350)	Data waiver enclosed (MRID 50521409).
Active Ingredient name discrepancy	Updated label enclosed

Active Ingredient concentration discrepancy	Updated CSFs enclosed
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In support of this of this response, enclosed please find the following documents:

- 1) Updated Product Label;
- 2) Basic and Alternate#1 Confidential Statements of Formula dated 2/06/2018;
- 3) Updated Generic Data Matrix (both Public and Agency copies);
- 4) Transmittal Document; and,
- 5) Data Waivers.

If you have any questions about this submission, please contact me at (202) 393-3903 ext. 119 or by email at georgia@lewisharrison.com.

Sincerely,

Georgia Anastasiou

Georgia Anastasiou
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)
Luke Zeitler (Lamplight)

EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: September 11, 2017
 STUDY SUBMITTER: Lamplight Farms
 4900 North Lilly Road
 Menomonee Falls, WI 53051
 PRODUCT: CLEANBURN
 EPA REG. NO.: 33025-
 REGULATORY ACTION: PRIA Code B673

STUDIES SUBMITTED:

- MRID: 50389801 CLEANBURN: Product Properties (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 9 pages, including 27 page confidential appendix.
- MRID: 50389802 CLEANBURN: Preliminary Analysis (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 4 pages.
- MRID: 50389803 Physical and Chemical Characteristics of Cleanburn with 3% Citronella: Color, Physical State, Odor, Oxidation/Reduction, Flammability, Storage Stability, Corrosion Characteristics, pH, Viscosity and Relative Density (September 19, 2017) by Brian A. Roe, Case Laboratories; Study No: 4780-06; 14 pages.
- MRID: 50389804 CLEANBURN: Summary of Acute Toxicity Data (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 4 pages.
- MRID: 50389805 CLEANBURN TORCH FUEL WITH 3% CITRONELLA OIL: Acute Oral Toxicity – Up and Down Procedure in Rats (September 1, 2017) by Carolyn Lowe, Product Safety Labs; Study No: 46226; 14 pages.
- MRID: 50389806 CLEANBURN TORCH FUEL WITH 3% CITRONELLA OIL: Primary Eye Irritation in Rabbits (September 1, 2017) by Carolyn Lowe, Product Safety Labs; Study No: 46227; 15 pages.
- MRID: 50389807 CLEANBURN TORCH FUEL WITH 3% CITRONELLA OIL: Primary Skin Irritation in Rabbits (September 1, 2017) by Carolyn Lowe, Product Safety Labs; Study No: 46228; 17 pages.
- MRID: 50389808 PALM KERNEL METHYL ESTER WITH 3% CITRONELLA OIL: Acute Oral Toxicity – Up and Down Procedure in Rats (September 1, 2017) by Melissa Slonina, Product Safety Labs; Study No: 46229; 14 pages.

MRID: 50389809 PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL:
Acute Oral Toxicity – Primary Eye Irritation in Rabbits (September 1,
2017) by Melissa Slonina, Product Safety Labs; Study No: 46230; 17
pages.

MRID: 50389810 PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL:
Acute Oral Toxicity – Primary Skin Irritation in Rabbits (September 1,
2017) by Melissa Slonina, Product Safety Labs; Study No: 46231; 17 pages

MRID: 50389811 CLEANBURN: Waiver Request for Acute Toxicity Testing (September
11, 2017) by Georgia Anastasiou, Lewis & Harrison; 5 pages.

COMPANY CONTACT: Georgia Anastasiou
Lewis & Harrison, LLC
123 C Street NW, Suite 505
Washington, DC 20001
(202) 393-3903 x119
georgia@lewisharrison.com

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001

telephone 202.393.3903
fax 202.393.3906

September 13, 2017

E-Submission

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Andrew Bryceland
Biopesticides and Pollution Prevention Division

SUBJECT: Lamplight Farms, Inc.
CLEANBURN (33025-__)
Application to Register End Use Product
PRIA Category B673

Dear Mr. Bryceland:

On behalf of Lamplight Farms, Inc., I am submitting an application to register the end-use product, CLEANBURN. This product contains 3% citronella oil as the active ingredient and will be used as an outdoor torch fuel to repel flying insects. This product is similar in composition and use to the currently registered product *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3, with the exception of the inert ingredients.

In support of this registration, I am submitting product chemistry data and acute toxicity data. As for efficacy data requirements Lamplight wishes to use the "cite-all" option. Both *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3 and CLEANBURN contain 3% oil of citronella as the active ingredient. As stated above, with the exception of the inert ingredients, which are expected to have no impact on efficacy, this formula is the same as the formula for *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3.

I believe the PRIA Category code for this registration falls under B673 since the source of TGA1 for the citronella oil is the same as *Tiki Insect Repellent Monarch 1101A*.

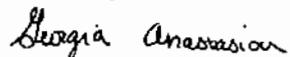
In support of this application, enclosed please find the following documents:

- 1) Application for Pesticide Registration;
- 2) Payment Receipt;
- 3) Propose Product Label;
- 4) Basic and Alternate#1 Confidential Statements of Formula dated 9/11/2017;

- 5) Certification with Respect to Data Compensation;
- 6) End-Use Data Matrix (both Public and Agency copies);
- 7) Generic Data Matrix (both Public and Agency copies);
- 8) Transmittal Document; and,
- 9) Product Chemistry & Acute Toxicity data.

Thank you for in advance for your help with this request. If you have any questions about this submission, please contact me at (202) 393-3903 ext. 19 or by email at georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)
Luke Zeitler (Lamplight)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 17, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

LEWIS & HARRISON, LLC
LAMPLIGHT FARMS, INC.
122 C STREET, N.W., SUITE 505
WASHINGTON, DC 20001

Report of Analysis for Compliance with PR Notice 11-03

Thank you for your submittal of 06-OCT-17. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 11-03. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.

EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: September 11, 2017
 STUDY SUBMITTER: Lamplight Farms
 4900 North Lilly Road
 Menomonee Falls, WI 53051
 PRODUCT: CLEANBURN
 EPA REG. NO.: 33025-
 REGULATORY ACTION: PRIA Code B673

STUDIES SUBMITTED:

- MRID: 50389801 CLEANBURN: Product Properties (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 9 pages, including 27 page confidential appendix.
- MRID: 50389802 CLEANBURN: Preliminary Analysis (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 4 pages.
- MRID: 50389803 Physical and Chemical Characteristics of Cleanburn with 3% Citronella: Color, Physical State, Odor, Oxidation/Reduction, Flammability, Storage Stability, Corrosion Characteristics, pH, Viscosity and Relative Density (September 19, 2017) by Brian A. Roe, Case Laboratories; Study No: 4780-06; 14 pages.
- MRID: 50389804 CLEANBURN: Summary of Acute Toxicity Data (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 4 pages.
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- MRID: 50389808 PALM KERNEL METHYL ESTER WITH 3% CITRONELLA OIL: Acute Oral Toxicity – Up and Down Procedure in Rats (September 1, 2017) by Melissa Slonina, Product Safety Labs; Study No: 46229; 14 pages.

- MRID: 50389809** **PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL:**
Acute Oral Toxicity – Primary Eye Irritation in Rabbits (September 1, 2017) by Melissa Slonina, Product Safety Labs; Study No: 46230; 17 pages.
- MRID: 50389810** **PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL:**
Acute Oral Toxicity – Primary Skin Irritation in Rabbits (September 1, 2017) by Melissa Slonina, Product Safety Labs; Study No: 46231; 17 pages
- MRID: 50389811** **CLEANBURN: Waiver Request for Acute Toxicity Testing** (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 5 pages.

COMPANY CONTACT: Georgia Anastasiou
Lewis & Harrison, LLC
123 C Street NW, Suite 505
Washington, DC 20001
(202) 393-3903 x119
georgia@lewisharrison.com

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001
telephone 202.393.3903
fax 202.393.3906

September 13, 2017

E-Submission

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: Andrew Bryceland
Biopesticides and Pollution Prevention Division

SUBJECT: Lamplight Farms, Inc.
CLEANBURN (33025-___)
Application to Register End Use Product
PRIA Category B673

Dear Mr. Bryceland:

On behalf of Lamplight Farms, Inc., I am submitting an application to register the end-use product, CLEANBURN. This product contains 3% citronella oil as the active ingredient and will be used as an outdoor torch fuel to repel flying insects. This product is similar in composition and use to the currently registered product *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3, with the exception of the inert ingredients.

In support of this registration, I am submitting product chemistry data and acute toxicity data. As for efficacy data requirements Lamplight wishes to use the "cite-all" option. Both *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3 and CLEANBURN contain 3% oil of citronella as the active ingredient. As stated above, with the exception of the inert ingredients, which are expected to have no impact on efficacy, this formula is the same as the formula for *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3.

I believe the PRIA Category code for this registration falls under B673 since the source of TGAI for the citronella oil is the same as *Tiki Insect Repellent Monarch 1101A*.

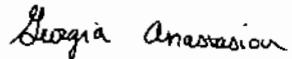
In support of this application, enclosed please find the following documents:

- 1) Application for Pesticide Registration;
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- 4) Basic and Alternate#1 Confidential Statements of Formula dated 9/11/2017;

- 5) Certification with Respect to Data Compensation;
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- 9) Product Chemistry & Acute Toxicity data.

Thank you for in advance for your help with this request. If you have any questions about this submission, please contact me at (202) 393-3903 ext. 19 or by email at georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)
Luke Zeitler (Lamplight)

Memorandum**E-SUBMISSION**Date: 10 / 18 / 17To: PM 91, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX FOR ACTIVE INGREDIENT

Date February 6, 2018		EPA Reg. No./File Symbol 33025-A		Page 1 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
880.1100	Product Identity & Composition	48649701	Lamplight Farms (33025)		
880.1200	Description of starting materials, production & formulation process used to produce product	48649701	Lamplight Farms (33025)		
880.1400	Discussion of formation of impurities	48649701	Lamplight Farms (33025)		
830.1700	Preliminary analysis	48649702	Lamplight Farms (33025)		
830.1750	Certified Limits	41785703	Candle Corp (009201)	OLD	(1)
830.1800	Enforcement analytical method	48649702	Lamplight Farms (33025)		
830.6302	Color	41785703	Candle Corp (009201)	OLD	(1)
830.6303	Physical State	41785703	Candle Corp (009201)	OLD	(1)
830.6304	Odor	41785703	Candle Corp (009201)	OLD	(1)
830.6313	Stability	41785703	Candle Corp (009201)	OLD	(1)
830.6315	Flammability	41785703	Candle Corp (009201)	OLD	(1)
830.6317	Storage Stability	41785703	Candle Corp (009201)	OLD	(1)
830.6319	Miscibility	41785703	Candle Corp (009201)	OLD	(1)
830.6320	Corrosion Characteristics	41785703	Candle Corp (009201)	OLD	(1)
830.7000	pH	41785703	Candle Corp (009201)	OLD	(1)
830.7100	Viscosity	41785703	Candle Corp (009201)	OLD	(1)
830.7200	Melting point	41785703	Candle Corp (009201)	OLD	(1)
830.7220	Boiling point	41785703	Candle Corp (009201)	OLD	(1)
830.7300	Density	41785703	Candle Corp (009201)	OLD	(1)
830.7520	Particle Size	N/A			(2)
830.7550-830.7570	Partition coefficient	N/A			(3)
830.7840	Water solubility	41785703	Candle Corp (009201)	OLD	(1)
830.7950	Vapor Pressure	41785703	Candle Corp (009201)	OLD	(1)

Signature

Georgia Anastasiou

Name and Title:

Georgia Anastasiou, Agent for Lamplight Farms Inc.

Date

February 6, 2018



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX FOR ACTIVE INGREDIENT

Date February 6, 2018		EPA Reg. No./File Symbol 33025-A		Page 2 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
TOXICOLOGY					
870.1100	Acute Oral Toxicity	41747402 43179401	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.1200	Acute Dermal Toxicity	41747403 43167101	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.1300	Acute Inhalation Toxicity	41747404 43167102	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.2400	Primary Eye Irritation	41747405 43167103	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.2500	Primary Dermal Irritation	41747406 43167104	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
870.2600	Dermal Sensitization	41747407 43167105	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
	Hypersensitivity				Not Applicable
870.5385/870.5895	Microbial mutagenicity	41786701 41785702 41747408	Citronella Joint Venture (67736) Citronella Joint Venture (67736) Candle Corp (009201)	OLD OLD OLD	(1)
870.3550	Immunotoxicity	50521401	Lamplight Farms (33025)		
870.3100	90-Day oral toxicity	50521402	Lamplight Farms (33025)		
870.3250	90-Day dermal toxicity	50521403	Lamplight Farms (33025)		
870.3465	90-Day inhalation toxicity	50521404	Lamplight Farms (33025)		
870.3700	Prenatal Development	50521405	Lamplight Farms (33025)		

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date February 6, 2018
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX FOR ACTIVE INGREDIENT

Date February 6, 2018		EPA Reg. No./File Symbol 33025-A		Page 3 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ECOLOGICAL EFFECTS					
850.2100	Acute Avian Oral	41747409	Candle Corp (009201)	OLD	(1)
850.2200	Avian Dietary Toxicity	50521406	Lamplight Farms (33025)	-	
154B-8	Fish toxicity	41747410	Candle Corp (009201)	OLD	(1)
154B-9	Invertebrate Toxicity	41747411	Candle Corp (009201)	OLD	(1)
850.4100	Seedling emergence	50521407	Lamplight Farms (33025)		
850.4250	Vegetative vigor	50521408	Lamplight Farms (33025)		
880.4350	Nontarget insects	50521409	Lamplight Farms (33025)	-	
ENVIRONMENTAL FATE					
					Non-Applicable

FOOTNOTES

1. Per pages 27-28 of the Oil of Citronella RED, these generic data requirements have been fulfilled.
2. The dissociation constant data requirement is not applicable since citronella does not have any dissociable groups.
3. The partition coefficient data requirement is not applicable since citronella is not a non-polar organic substance.

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date February 6, 2018
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DATA MATRIX FOR ACTIVE INGREDIENT

Date	February 6, 2018	EPA Reg. No./File Symbol	33025-A	Page 1 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
880.1100	Product Identity & Composition	48649701	Lamplight Farms (33025)		
880.1200	Description of starting materials, production & formulation process used to produce product	48649701	Lamplight Farms (33025)		
880.1400	Discussion of formation of impurities	48649701	Lamplight Farms (33025)		
830.1700	Preliminary analysis	48649702	Lamplight Farms (33025)		
830.1750	Certified Limits	41785703	Candle Corp (009201)	OLD	(1)
830.1800	Enforcement analytical method	48649702	Lamplight Farms (33025)		
830.6302	Color	41785703	Candle Corp (009201)	OLD	(1)
830.6303	Physical State	41785703	Candle Corp (009201)	OLD	(1)
830.6304	Odor	41785703	Candle Corp (009201)	OLD	(1)
830.6313	Stability	41785703	Candle Corp (009201)	OLD	(1)
830.6315	Flammability	41785703	Candle Corp (009201)	OLD	(1)
830.6317	Storage Stability	41785703	Candle Corp (009201)	OLD	(1)
830.6319	Miscibility	41785703	Candle Corp (009201)	OLD	(1)
830.6320	Corrosion Characteristics	41785703	Candle Corp (009201)	OLD	(1)
830.7000	pH	41785703	Candle Corp (009201)	OLD	(1)
830.7100	Viscosity	41785703	Candle Corp (009201)	OLD	(1)
830.7200	Melting point	41785703	Candle Corp (009201)	OLD	(1)
830.7220	Boiling point	41785703	Candle Corp (009201)	OLD	(1)
830.7300	Density	41785703	Candle Corp (009201)	OLD	(1)
830.7520	Particle Size	N/A			(2)
830.7550-830.7570	Partition coefficient	N/A			(3)
830.7840	Water solubility	41785703	Candle Corp (009201)	OLD	(1)
830.7950	Vapor Pressure	41785703	Candle Corp (009201)	OLD	(1)

Signature

Georgia Anastasiou

Name and Title:

Georgia Anastasiou, Agent for Lamplight Farms Inc.

Date

February 6, 2018



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUN 18 2018

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

****CONTAINS CONFIDENTIAL BUSINESS INFORMATION****

BY EMAIL
RETURN RECEIPT REQUESTED

Georgia Anastasiou
Lamplight Farms, Inc.
c/o Lewis & Harrison, LLC
122 C Street, N.W., Suite 505
Washington, DC 20001

Subject: 75-day Deficiencies: Product Performance Data (40 CFR § 158.2160) and Product Chemistry Data (40 CFR § 158.2030) Deficiencies.
Application for Registration Dated September 11, 2017
EPA Receipt Date: October 06, 2017
Product Name: Clean burn (a.i.: Oil of Citronella)
EPA File Symbol: 33025-A
OPP Decision Number: 534726

Dear Mrs. Anastasiou:

The U.S. Environmental Protection Agency (EPA or Agency) has received and begun its in-depth review of the subject application and has determined that it is incomplete and that further information is needed. This letter is a written notification of those deficiencies and identifies your options under 40 CFR § 152.105 and Section 33 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by the Pesticide Registration Improvement Extension Act (PRIA 3). Your options under 40 CFR § 152.105 and Section 33 of FIFRA are addressed separately because each involves a different time frame and set of options for responding to this letter. Please ensure that you consider each of the sections below in determining how and when you respond to this letter.

40 CFR § 152.105

In accordance with 40 CFR § 152.105, you are allowed 75 days from the date of this letter, ending 09 01, 2018, to provide a response concerning the deficiencies listed in this letter. Your response may include making corrections to complete the application, or notifying the EPA of the date on which you expect to complete the application, or withdrawing your application. If you do not respond to this letter within 75 days or if you respond with a date on which you expect to complete the application but fail to meet that scheduled date, the EPA will treat the application as if you had withdrawn it. Withdrawal

concludes the EPA's review of your application. Any subsequent submission of the same application must then be submitted as a new application with a new deadline for the EPA to make a determination on your application and subject to a new registration service fee.

At this time, the EPA has identified the following deficiencies in its review of the subject application:

- 1) The cited MRID's for the physical chemical data requirements below did not include the methods that were used. Methods used in determining the following physical/chemical characteristics for Citronella oil must be provided. RED

Cite All

OCSP 830.6313 Stability to normal and elevated temperatures, metals and metal ions;
OCSP 830.6315 Flammability;
OCSP 830.6317 Storage Stability
OCSP 830.6320 Corrosion characteristics
OCSP 830.7300 Density/Relative Density/Bulk Density, and
OCSP 830.7950 Vapor pressure.

- 2) The cited MRID's for the physical chemical data requirements below did not include numerical values and methods that were used. Measurable numerical values and method of determination for these physical/chemical characteristics of Citronella oil must be provided.

Cite All

OCSP 830.7000 pH;
OCSP 830.7050 UV/ Visible light absorption;
OCSP 830.7100 Viscosity;
OCSP 830.7220 Boiling point;
OCSP 830. 7550, 830.7560,
OCSP 830.7570 Partition Coefficient (n-Octanol/water), and
OCSP 830.7840 Water solubility.

- write M.F. Policy*
- 3) The manufacturing process of the end-use product. Clean burn, is described in MRID 503898-01. However, the quantity of each ingredient used in the formulation of the product is not reported and the packaging and packaging material is not described. You must report the quantity of each ingredient used in the formulation during production process, and describe packaging and packaging material. *Fixed Data Sec. Sample product label as needed*

- Use as dependent*
- 4) Product performance data must be submitted and, specifically, should support all claims against public health pests appearing on the product label. You chose the "cite all" method to satisfy product performance data requirement, however, no efficacy study has been found suitable for characterizing efficacy of the proposed product against mosquitoes in the USA. Specifically, product performance data is needed for determination of space of effective repellency covered by one canister, how many burning canisters are needed for effective coverage of a given space, and how to place canisters for optimal coverage of a given space.

- 5) You must revise the proposed product label to include the following use instructions:

If there's no data,

Data Gap. EPA product -

- Do not use in windy conditions.
- Do not tip torch as fuel can spill and cause fire.
- Do not use gasoline or other combustible or flammable fluids.
- Do not place torch under covered shelter.
- Do not place torch near pedestrian traffic, wood, clothing or dry vegetation.
- Adjust wick height no higher than ¾ inches.
- Keep clothing, hair and face away from flame.
- To extinguish flame, place snuffer cap completely over wick until flame is extinguished.

Further review of your application and your response to the deficiencies may identify additional deficiencies and you will be so informed.

FIFRA Section 33/PRIA

This application is also subject to a deadline for making a determination on this application under FIFRA Section 33, Pesticide Registration Service Fees, established under the Pesticide Registration Improvement Act of 2003 (PRIA). The time frame for the EPA to make a determination on this application ends on 08 31 2018. Because the deadline for the EPA to make a determination on this application expires before the end of the 75 days you have to respond to the deficiencies noted above, you have the following three options:

1. **Establish a New Due Date and Resolve the Issues.** You may work with us to establish a new Section 33/PRIA deadline that allows for an appropriate response to the 75-day letter. If you choose this option, you need to contact the EPA no later than 08 17, 2018, to discuss a time frame that allows you to address the deficiencies listed above and the EPA to make a regulatory decision.
2. **Withdraw the Application.** Alternatively, you may notify us no later than 08 17, 2018, that you are withdrawing your application. As discussed previously in this letter, withdrawal concludes the EPA's review of your application; however, you may resubmit your application after the deficiencies have been addressed. Should you choose to resubmit your application, it would be subject to a new deadline for making a determination on your application and a new registration service fee. Since a fee was paid, the EPA will provide any applicable refund as soon as practicable.¹
3. **Not Respond.** If the EPA does not hear from you by 08 17, 2018, the Agency, in meeting its obligation under Section 33/PRIA, may issue a determination to not grant your application. While a determination to not grant an application would allow the EPA to have met its obligation under Section 33 of FIFRA to issue a determination by a specified date, this determination is neither a denial of the application pursuant to Section 3(c)(6) of FIFRA or withdrawal of the application. Thus, the EPA will continue to diligently work on any such application as long as the EPA receives a response to a deficiency notice within the 75 days described previously in this letter.


Please respond to this letter by 08 17, 2018, by contacting Menyon Adams by telephone at (703) 347-8496 or via email at adams.menyon@epa.gov, with a response and for any questions concerning this

¹ See <http://www2.epa.gov/pria-fees/overview-pria-fee-reduction-and-refund-formula> for more information on refunds.

Page 4 of 4
EPA File Symbol 33025-A
OPP Decision No. 534726

letter. When submitting information or data in response to this letter, a copy of this letter should accompany the submission to facilitate processing.

Sincerely,



for Linda Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Citronella oil
PC Codes: 021901

Sci. Science review for new EP with unregistered source of a.i.
DP Number(s): 445771
EPA Reg. or File Symbol No: 33025-A



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

MEMORANDUM

DATE: 05/15/2018

SUBJECT: Science Review in support of registration of new end-use product, Cleanburn, containing 3% w/w Citronella oil as its active ingredient from unregistered source.

Decision Number:	534726
DP Number:	445771
EPA File Symbol Number:	33025-A
Chemical Class:	Biochemical
PC Code:	021901
CAS Number:	8000-29-1
Active Ingredients:	Citronella oil
Tolerance Exemptions:	Non-food
MRID Numbers:	505214-01 thru 505214-09

FROM: Clara Fuentes, PhD.
Entomologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

THRU: Catherine Eiden, Senior Advisor

Risk Assessment Branch
Biopesticides & Pollution Prevention Division

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Lewis & Harrison Consultants in Government Affairs on behalf of Lamplight Farms, Inc. is requesting registration of a citronella-based mosquito repellent, Cleanburn, containing an unregistered source of active ingredient, Citronella oil, corresponding to the commercial variety "Java," extracted from *Cymbopogon winterianus*. The registrant is fulfilling product chemistry data requirements for the unregistered active ingredient in Cleanburn with data previously submitted for registration of Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3). The source for the oil of citronella in Monarch 1101A and Cleanburn is identical. The source of Citronella in Cleanburn remains unchanged from the time of the original registration of Monarch 1101A, and thus the registrant is bridging to MRIDs 486497-01, 486497-03, and 417857-03 respectively, for Manufacturing process of the active ingredient, Citronella oil, Discussion on formation of impurities; Enforcement analytical method that was employed for quantification of Citronella oil present in Monarch 1101A, and Physical/Chemical characteristics of Citronella oil Technical. The registrant references MRID 486497-02 in MRID 503898-02 for Preliminary Analysis of Citronella oil that was conducted for registration of Monarch 1101A.

Data on Product Identity & Composition, Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for End-Use product, Cleanburn, is provided in MRID 503898-01. Data on Physical/Chemical Characteristics of end-use product, Cleanburn, is provided in MRID 503898-03.

Tier I acute mammalian toxicity for the end-use product, Cleanburn, has been addressed with data in MRID 503898-05 for Acute oral; MRID 503898-06 for Acute eye irritation, and MRID 503898-07 for Acute dermal irritation.

Tier I acute mammalian toxicity for the active ingredient, Citronella oil, has been addressed by bridging to MRID 431794-01 for Acute oral; MRID 431671-01 for Acute dermal; MRID 431671-02 for acute inhalation; MRID 431671-03 for Acute eye irritation; MRID 431671-04 for Acute dermal irritation, and MRID 431671-05 for Skin sensitization. These toxicity studies correspond to Citronella oil, commercial variety "Java."

Tier I subchronic mammalian toxicity data, required for the active ingredient supplied from unregistered source, have been addressed with rationale in MRID 503898-11 for waiving further studies. MRID 503898-11 references mutagenicity data in MRIDs 417857-01 and 417857-02, and Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105) with references therein.

Non-target organisms' data requirements are addressed by bridging to data on Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*), A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*), and A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*) in MRIDs 417474-09, 417474-10, and MRID 417474-11, respectively.

Required data on Non-target plants and non-target insects, OCSPP 850.4000 and OCSPP 850.3020, respectively, is waived based on minimal exposure to plants and insects given the use pattern of the product, and the repellent effect of citronella oil on insects.

Lastly, product performance data is addressed by the cite all method. In addition, this submission includes copies of product label, CSF for basic and alternate formulations, dated 2/06/2018, and updated data matrix to address deficiencies identified by the Agency in an Agency's deficiency letter, dated on January 29, 2018.

BACKGROUND INFORMATION

The proposed product, Cleanburn, contains 3% w/w Citronella oil, corresponding to the commercial variety "Java," extracted from *Cymbopogon winterianus*. The source and percent concentration of the active ingredient, Citronella oil (Java variety), present in both, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3) and proposed product, Cleanburn, are identical. Thus, the registrant is bridging to product chemistry data submitted for registration of Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3) to satisfy product chemistry data requirements for Citronella oil in Cleanburn that is supplied by same unregistered supplier and present at the same concentration as in referenced product, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3). Cleanburn is a torch fuel formulation to be used outdoors as space repellent against mosquitoes. Label use directions instructs users to pour the content from the original container into vessel, canister or burner and wipe away any excess before lighting. The label doesn't specify space of effective repellency covered by one canister, or how many burning canisters are needed for effective coverage of a given space.

RECOMMENDATIONS AND CONCLUSIONS

Product chemistry:

- 1 The registrant has adequately addressed product chemistry data requirements for end-use product, Cleanburn, and its active ingredient, Citronella oil, **except for the following deficiencies concerning Physical/Chemical characteristics of the active ingredient.** These data are bridged from MRID 417857-03 (Refer to Table 1). Referenced MRID 417857-03 doesn't provide methods for determination of Stability, Storage stability and corrosion characteristics, flammability, relative density or specific gravity, and vapor pressure. MRID 417857-03 doesn't provide quantifiable measurement of PH, visible light absorption, viscosity, boiling point, partition coefficient, and water solubility. These deficiencies listed below, should be resolved:
 - 1a) The registrant needs to **report the methods employed for determination of the following physical/chemical characteristics** for Citronella oil:
 - OCSP 830.6313 Stability to normal and elevated temperatures, metals and metal ions;
 - OCSP 830.6315 Flammability;
 - OCSP 830.6317 Storage Stability and
 - OCSP 830.6320 Corrosion characteristics

OCSPP 830.7300 Density/Relative Density/Bulk Density, and
OCSPP 830.7950 Vapor pressure.

1b) **Measurable numerical values and method of determination are needed** for these physical/chemical characteristics of Citronella oil:

OCSPP 830.7000 pH;
OCSPP 830.7050 UV/ Visible light absorption;
OCSPP 830.7100 Viscosity;
OCSPP 830.7220 Boiling point;
OCSPP 830.7550, 830.7560, and OCSPP 830.7570 Partition Coefficient (n-Octanol/water), and
OCSPP 830.7840 Water solubility.

- 2 Manufacturing process of Cleanburn is described in MRID 503898-01. However, **quantity of each ingredient used in the formulation of the product is not reported, and it should be reported, together with description of packaging material. Please, upgrade MRID 503898-01 by reporting amount of each component added to the formulation during production process, and describe packaging and packaging material.**

Classification of submitted studies for product chemistry:

Cited MRID 486497-01, Manufacturing process of the active ingredient, Citronella oil, and Discussion on formation of impurities is acceptable. (Refer to Confidential Appendix for details).

MRID 503898-02, bridging to MRID 486497-02 for Preliminary Analysis of Citronella oil, is acceptable. (Refer to Confidential Appendix for details).

Cited MRID 486497-03, is acceptable. Enforcement analytical method employed for quantification of Citronella oil present in Monarch 1101A, containing 3% w/w Citronella oil from same unregistered source as Cleanburn, is suitable for quantification of Citronella oil content in Cleanburn. Citronella oil is present at same concentration in both products, and it is supplied from same unregistered source.

MRID 503898-01, Product Identity & Composition, Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for End-Use product, Cleanburn, is **acceptable, pending revision of the manufacturing process. Steps followed during manufacturing process are described on pg. 22 and 23 in MRID 503898-01. However, quantity of each ingredient used in the formulation of the product is not specified, and it should be reported, together with information on packaging material.** This volume also addresses product identity and composition of the active ingredient, Citronella oil. Refer to Confidential Appendix for details on product composition, manufacturing process and analytical methods.

Cited MRID 417857-03, Physical Chemical Characteristics of Citronella oil are **unacceptable**. The registrant needs to provide data for some of the physical/chemical data requirements that have not been properly addressed neither with applicable rationale nor with numerical values. For example, neither method of determination nor numerical measurement are provided for the following data: OCSPP 830.7000 pH; OCSPP 7050 UV/Visible light absorption; OCSPP 830.7100 Viscosity; OCSPP 830.7220 Boiling point; OCSPP 830.7550, OCSPP 830.7560, and OCSPP 830.7570 Partition Coefficient (n-Octanol/water), and OCSPP 830.7840 Water solubility. In addition, methods employed for determination of the following physical/chemical characteristics of Citronella oil need to be reported: OCSPP 830.6317 Storage Stability and OCSPP 830.6320 Corrosion characteristics; OCSPP 830.6313 Stability to normal and elevated temperatures, metals and metal ions; OCSPP 830.6315 Flammability; OCSPP 830.7300 Density/Relative Density/Bulk Density; OCSPP 830.7950 Vapor pressure. (Refer to Table 1, and to item # 1 and # 2 in list of deficiencies, above). Cited MRID 417857-03 doesn't provide this information.

MRID 503898-03, Physical/Chemical Characteristics of End-Use product, Cleanburn, is acceptable (Refer to Table 2).

Refer to Tables 1 and 2 for Physical Chemical Characteristics of Citronella oil and Cleanburn product, respectively.

Acute Mammalian Toxicity

Tier I Acute mammalian toxicity data for Citronella oil is acceptable. These data requirements have been adequately addressed by bridging to MRID 431794-01 for Acute oral; MRID 431671-01 for Acute dermal; MRID 431671-02 for acute inhalation; MRID 431671-03 for Acute eye irritation; MRID 431671-04 for Acute dermal irritation, and MRID 431671-05 for Skin sensitization. These cited studies correspond to Citronella oil, commercial variety "Java." Citronella oil is categorized under toxicity category III for acute oral, acute dermal toxicity, acute eye irritation, and acute dermal irritation, and under toxicity category IV for acute inhalation and skin sensitization.

Tier I Acute mammalian toxicity data for end-use product, Cleanburn, has been adequately addressed with data in MRID 503898-05 for acute oral; MRID 503898-06 for acute eye irritation, and MRID 503898-07 for acute dermal irritation.

MRIDs 503898-05, 503898-06 and 503898-07 for Acute oral, Acute Eye irritation, and Acute dermal irritation, respectively, are acceptable.

MRID 503898-11, Study waiver request for Acute dermal, Acute inhalation, and Skin sensitization is acceptable. The registrant's rationale is based on the composition of the formulation (Refer to Confidential Appendix for product composition), use pattern (not for intentional application to human skin), and low toxicity profile of Citronella oil (toxicity category III for acute dermal, and toxicity category IV for acute inhalation and skin sensitization).

MRIDs 505214-01 thru 505214-05 are acceptable. These MRIDs cite Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), with referenced MRID studies therein, in support for waiving Tier I subchronic toxicity studies.

MRID 505214-01 Waiver request for immunotoxicity studies is supported by referenced data in MRIDs 417857-01, and 417857-02. Data in these studies show that Citronella oil is not mutagenic.

MRID 505214-02, Rationale, in support of waiving 90-day oral study is based on the use pattern of Cleanburn that will be used as torch fuel. Therefore, oral exposure is not anticipated.

MRID 505214-03 Rationale in support of waiving 90-day dermal study is based on the use pattern of Cleanburn that will be used as torch fuel. Therefore, intentional or prolonged exposure to the product from application to human skin is unlikely.

MRIDs 505214-04 and 505214-05, Request for waiving 90-day Inhalation and Developmental toxicity studies, respectively, is based on Reregistration Eligibility Decision for Oil of Citronella (CASE 3105). These data requirements have been waived in the Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), based on the low toxicity profile of Citronella oil (Commercial variety "Java," which is slightly toxic).

Non-target organisms:

MRID 417474-09, Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*) is acceptable.

Data on required Avian subacute dietary toxicity study, OSCPP 850.2200, is waived based on low acute oral toxicity. Oil of citronella is classified as Non-toxic to birds via the oral route. Furthermore, based on its use pattern, ingestion of the proposed product by birds is not expected.

MRID 417474-10, A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*) is acceptable. Oil of citronella has been classified as slightly toxic to fresh water fish.

MRID 417474-11, A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*) is acceptable. Oil of citronella has been classified as slightly toxic to aquatic invertebrates.

Required data on Non-target plants and non-target insects, OCSPP 850.4000 and OCSPP 850.3020, respectively, ~~is~~ are waived based on minimal exposure to plants and insects given the use pattern of the product, and the repellent effect of citronella oil on insects.

Product performance: **Unacceptable.**

Product performance data is required and needs to be submitted in support of efficacy claim against mosquitoes on the product label. The registrant is resorting to the "cite all" method to satisfy product performance data requirement, however, no efficacy study has been found

suitable for characterizing efficacy of the proposed product against mosquitoes in the USA. Thus, efficacy data on the proposed product need to be submitted ~~unless the registrant can submit efficacy data from me-too product, Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85). Efficacy data cited from Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85) is not in file with the Agency database.~~ Specifically, product performance data should be provided ~~is needed~~ for determination of space of effective repellency covered by one canister, how many burning canisters are needed for effective coverage of a given space, and how to place canisters for optimal coverage of a given space.

Note to RAL

In addition, the product label should provide the following ~~information~~ directions concerning use instructions:

Do not use in windy conditions,
 Do not tip torch as fuel can spill and cause fire.
 Do not use gasoline or other combustible or flammable fluids
 Do not place torch under covered shelter
 Do not do not place torch near pedestrian traffic, wood, clothing or dry vegetation
 Adjust wick height no higher than ¾ inches.
 Keep clothing, hair and face away from flame
 To extinguish flame, place snuffer cap completely over wick until flame is extinguished.

CONCLUSION

Based on the ~~review of available data referenced by the registrant on~~ product use pattern and composition, toxicological profile of oil of citronella, and its non-toxic mode of action, no anticipated adverse effects to human health, ~~to~~ nontarget organisms, or the environment are expected from application of the proposed product when used according to label directions. However, no efficacy study on file has been found suitable for characterizing efficacy of the proposed product, Cleanburn, against mosquitoes in the USA. Thus, efficacy data on the proposed product need to be submitted unless the registrant can submit efficacy data from me-too product, Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85). Efficacy data cited from Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85) is not in file with the Agency database. Specifically, product performance data should be provided for determination of space of effective repellency covered by one canister, or how many burning canisters are needed for effective coverage of a given space.

STUDY SUMMARY

Product Chemistry:

TABLE 1. Physical and Chemical Properties for Citronella oil

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Light amber	Visual observation
830.6303 Physical State	liquid	Visual observation
830.6304 Odor	Floral, grassy	Olfactory
830.6313 Stability	Unstable in the presence of alkali. Unstable in the presence of acids (esterification may take place), many strong inorganic acids can cause decomposition and/or polymerization on prolong exposure to UV light in the presence of air.	Not provided
830.6315 Flammability	170 °C	Not provided
830.6317 Storage Stability	Stable under normal conditions.	Not provided
830.6319 Miscibility	N/A The product is not emulsible liquid to be diluted with petroleum solvents	
830.6320 Corrosion Characteristics	Not corrosive	Method not provided
830.7000 pH	Unknown Not provided	
830.7050 UV/ Visible light absorption	Unaddressed	
830.7100 Viscosity	Unknown.	Not provided
830.7200 Melting point/ melting range	N/A	Not a solid
830.7220 Boiling point	170 °C	Not provided
830.7300 Density/Relative Density/Bulk Density	0.891 – 0.901 g/mL	Not provided

TABLE 1. Physical and Chemical Properties for Citronella oil

Guideline Reference No./Property	Description of Result	Methods
830.7520 Particle size, fiber length, diameter distribution	N/A	N/A water soluble and no fibrous substance
830.7550 830.7560 830.7570 Partition Coefficient (n-Octanol/water)	Doesn't dissociate. No numerical value provided	No method of measurement reported
830.7840 Water solubility	Soluble. No numerical value provided	No method of measurement reported
830.7950 Vapor pressure	There is no vapor pressure measurement available for Oil of Citronella, the values given are for the six constituents present in the greatest amounts: Camphene* 3.0 mm Hg at 20°C (est) Limonene 1.4 mm Hg at 25°C Citronellal 0.23 mm Hg at 20°C Geraniol 0.02 mm Hg at 20°C Citronellol 0.015 mm Hg at 25°C Me-isoeugenol* 0.01 mm Hg at 2QPC	Values marked with a * are estimated, all others have been taken from Flavor & Fragrance Ingredient data Sheets compiled by EMARIFM-FMA.

Data from MRID 417857-03

TABLE 2. Physical and Chemical Properties for Cleanburn (basic and alternate formulations)		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	N/A	N/A for EP
830.6303 Physical State	liquid	Visual observation
830.6304 Odor	N/A	N/A for EP
830.6313 Stability	N/A	N/A for EP
830.6315 Flammability	N/A	The product doesn't contain combustible liquids
830.6317 Storage Stability	65% geraniol after 14 days at 54°C ± 2°C.	Chromatographic analysis Geraniol peak area percent indicates percent geraniol in the product
830.6319 Miscibility	N/A	The product is not emulsible liquid to be diluted with petroleum solvents.
830.6320 Corrosion Characteristics	No signs of corrosion were noted on the commercial packing material, polyethylene terephthalate.	Visual inspection
830.7000 pH	5.37	pH meter
830.7100 Viscosity	2.5237 mm ² /s (cSt)	Ubbelohde viscometer
830.7300 Density/Relative Density/Bulk Density	0.8701 g/mL	CCL SOP 10.16 method

Data from MRID 503898-03

B. Acute Mammalian Toxicity

Table 3. Toxicological Profile of End-Use product, Cleanburn, Basic Formulation

MRID	Guideline	Test	Results LD ₅₀ /LC ₅₀	Toxicity Category
503898-05	870.1100	Acute Oral Toxicity	>5000 mg/kg	IV
503898-11	870.1200	Acute Dermal	Waiver	Waiver

MRID	Guideline	Test	Results LD ₅₀ /EC ₅₀	Toxicity Category
		Toxicity		
503898-11	870.1300	Acute Inhalation Toxicity	Waiver	Waiver
503898-06	870.2400	Primary Eye Irritation	Mildly irritating - free of irritation by 72 hours	III
503898-07	870.2500	Primary Dermal Irritation	Slightly irritating to skin	IV
503898-11	870.2600	Skin Sensitization	Waiver	Waiver

Table 4. Toxicological Profile of End-Use product, Cleanburn, Alternate Formulation

MRID	Guideline	Test	Results	Category
50389808	870.1100	Acute Oral Toxicity	>5000 mg/kg	IV
50389811	870.1200	Acute Dermal Toxicity	Waiver	Waiver
50389811	870.1300	Acute Inhalation Toxicity	Waiver	Waiver
50389809	870.2400	Primary Eye Irritation	Minimally irritating - free of irritation by 48 hours	III
50389810	870.2500	Primary Dermal Irritation	Slightly irritating to skin	IV
50389811	870.2600	Skin Sensitization	Waiver	Waiver

MRID 503898-11, Data waiver requests for Acute dermal, Acute inhalation, and Skin sensitization are based on the following rationale specific to each data requirement:

OCSPP 870.1200 Acute Dermal Toxicity:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 2:

"2. Required unless test material is corrosive to skin or has a pH between < 2 or 11.5 >." The pH of Cleanburn is 5.37.

In addition, under conditions of use, Cleanburn is not expected to result in dermal exposure.

OCSPP 870.1300 Acute Inhalation Toxicity:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 3:

"3. Required when the product consists of, or under conditions of use would result in, a respirable material (e.g., gas, volatile substances, or aerosol particulate)..."

Concerning Test Note 3, Cleanburn is a liquid and does not consist of a respirable material, such as a gas, vapor or particulate.

OCSPP 870.2600 Skin Sensitization:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 2 & 4:

"2. *Required unless test material is corrosive to skin or has a pH between < 2 or 11.5 >.*"

"4. *Required if repeated contact to human skin is likely to occur under conditions of use*"

Concerning Test Note 2, the pH of Cleanburn is 5.37.

Concerning Test Note 4, under conditions of use Cleanburn is not expected to result in repeated dermal exposure.

In addition, the battery of acute mammalian toxicity studies already conducted on Citronella oil show that Citronella oil is of low mammalian toxicity, classified under toxicity category III for acute oral, acute dermal, acute eye irritation, and acute dermal irritation, and under toxicity category IV for acute inhalation and skin sensitization.

Table 5. Toxicological Profile of Citronella oil

<u>Study Type/OCSPP Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID (Java variety)</u>
Acute Oral Toxicity/OCSPP 870.1100	> 4,860 mg/kg	III	431794-01
Acute Dermal Toxicity/OCSPP 870.1200	> 2,000 mg/kg	III	431671-01
Acute Inhalation Toxicity/OCSPP 870.1300	> 3.1 mg/L	IV	431671-02
Acute Eye Irritation/OCSPP 870.2400	Mild irritant	III	431671-03
Acute Dermal Irritation/OCSPP 870.2500	slightly irritant.	III	431671-04
Skin Sensitization/OCSPP 870.2600	Non- sensitizer	IV	431671-05
Hypersensitivity incidents	None reported		

The following Tier I Subchronic toxicity data are required for the active ingredient Citronella oil from an unregistered source; OCSPP 870.3100 90-day oral; OCSPP 870.3250 90-day dermal; OCSPP 90-day inhalation; OCSPP 870.3700 Prenatal development, and mutagenicity studies, OCSPP 870.5100 Bacterial reverse mutation test, and OCSPP 870.5300 / 870.5375 *In vitro*

mammalian cell assay, ~~are required for active ingredient Citronella oil from unregistered source.~~ The registrant is addressing these data requirements by bridging to data previously submitted for registration of Citronella oil technical (TGAI), and by providing the following rationale in support for waiving further testing:

According to the Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105), These data requirements were previously waived by the Agency for the following reasons:

1. The acute mammalian studies listed on Table 5, showed no significant adverse effects for various routes of exposure (Toxicity Category III for acute oral, dermal toxicity, acute eye irritation, and acute dermal irritation, and toxicity category IV for acute Inhalation and skin sensitization). (Refer to Table 5 for toxicological profile of Citronella oil).
2. The GRAS status of oil of citronella (21 CFR 182.2).
3. No report of hypersensitivity of adverse effects following oral and dermal exposure (which is currently accurate).
4. This rationale was used to develop and support an exemption under Section 25(b).

Specifically, the registrant has submitted MRIDs 505214-01 thru 505214-05 to address each Tier I subchronic toxicity data requirement individually:

MRID 505214-01, Waiver request for immunotoxicity.

The registrant is citing Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), with referenced MRID studies therein, in support for waiving additional immunotoxicity testing. According to the Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105), these data were previously waived by the Agency. Cited mutagenicity studies, Salmonella / mammalian microsome reverse mutation assay in MRIDs 417857-01, and *In vitro* Citogenetic Assay, measuring chromosomal frequencies in Chinese hamster ovary cells in MRID 417857-02, show that Citronella oil is not mutagenic. No increase in number of histidine revertants per plate with or without S9 (3300 µg/plate/+S9; 1,000 µg/plate/-S9, respectively) were reported in MRID 417857-01, and no chromosomal aberrations frequencies in Chinese hamster ovary with or without S9 (150 µg/plate/+S9; 75.5 µg/plate/-S9, respectively) were observed in MRID 417857-02 study.

MRID 505214-02, Waiver request for 90-day oral study is based on the following rationale:

According to the regulations in 40 CFR §158.2050, a 90-day oral toxicity study is required if the use pattern of the active ingredient is likely to result in repeated oral exposure to humans. Cleanburn will be used as torch fuel. Therefore, it is not expected that there would be any oral exposure.

~~Cleanburn will be used as torch fuel. Therefore, it is not expected that there would be any~~

oral exposure.

MRID 505214-03, Waiver request for 90-day dermal toxicity study is based on footnote #7 per 40 CFR §158.2050. According to the regulations in 40 CFR §158.2050, the data is required if the product is purposely applied to human skin. Cleanburn will be used as torch fuel. Therefore, it is not expected that there will be intentional or prolonged exposure to the product from application to human skin.

MRIDs 505214-04 and 505214-05, 90-day Inhalation and Developmental toxicity, respectively. These data requirements have been waived in the Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), based on the following rationale:

1. The acute mammalian studies listed on Table 5, showed no significant adverse effects by various routes of exposure (Toxicity Category III for acute oral, acute dermal toxicity, acute eye irritation, and acute dermal irritation, and toxicity category IV for acute Inhalation and skin sensitization). (Refer to Table 5 for toxicological profile of Citronella oil).
2. The GRAS status of oil of citronella (21 CFR 182.2).
3. No report of hypersensitivity of adverse effects following oral and dermal exposure (which is currently accurate).
4. This rationale was used to develop and support an exemption under Section 25(b).
5. Immunotoxicity data in referenced studies, MRIDs 417857-01 and 417857-02 show that Citronella oil is not mutagenic.

C. Non-Target Organisms

MRID 417474-09, Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*).

The acute oral LD₅₀ value for Northern bobwhite quail exposed to oil of citronella as a single oral dosage was greater than 2250 mg/kg. The LOAEL was 2,250 mg/kg. The NOAEL was 1,350 mg/kg, based on the reduction in body weight for all birds at 2250 mg/kg. Based on these values, oil of citronella is classified as Non-toxic to birds via the oral route.

MRID 417474-10, A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*)

The LC₅₀ > 17.3 mg/L is based on nominal concentration of oil of citronella. Oil of citronella has been classified as slightly toxic to fresh water fish.

MRID 417474-11, A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*).

The EC_{50} = 26.4 mg/L at 48 hours with 95% CL (13.0 mg – 36.0 mg oil of citronella). Based on these results, Oil of citronella has been classified as slightly toxic to aquatic invertebrates.

Data on required Avian dietary toxicity study, OSCPP 850.2200, is waived based on low acute oral toxicity. Oil of citronella is classified as Non-toxic to birds via the oral route. Furthermore, based on its use pattern, ingestion of the proposed product by birds is not expected

Data on Non-target plants and non-target insects, OCSP 850.4000 and 850.3020, respectively, have been waived based on minimal exposure to plants and insects given the use pattern of the product; and the repellent effect of citronella oil on insects.

Product Performance: No efficacy study on substantially similar product has been found. Therefore, efficacy studies in file for different, and no substantially similar formulations, are not suitable for characterizing performance of Cleanburn product. Product performance data is required ~~needed~~ for registration of Cleanburn; with a claim-claiming-of ~~with a claim-claiming-of~~ efficacy against mosquitoes.

cc: Clara Fuentes, RAL Menyon Adams, BPPD Chron File, IHAD/ARS FT, PY-S: 05/15/2018.

Citronella oil
PC Codes: 021901

Sci. Science review for new EP with unregistered source of a.i.
DP Number(s): 445771
EPA Reg. or File Symbol No: 33025-A



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION/OFFICE OF PESTICIDE PROGRAMS

MEMORANDUM

DATE: 05/15/2018

SUBJECT: Science Review in support of registration of new end-use product, Cleanburn, containing 3% w/w Citronella oil as its active ingredient from unregistered source.

Decision Number:	534726
DP Number:	445771
EPA File Symbol Number:	33025-A
Chemical Class:	Biochemical
PC Code:	021901
CAS Number:	8000-29-1
Active Ingredients:	Citronella oil
Tolerance Exemptions:	Non-food
MRID Numbers:	505214-01thru 505214-09

FROM: Clara Fuentes, PhD.
Entomologist
Risk Assessment Branch
Biopesticides & Pollution Prevention Division (7511P)

THRU: Catherine Eiden, Senior Advisor

Risk Assessment Branch
Biopesticides & Pollution Prevention Division

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

Lewis & Harrison Consultants in Government Affairs on behalf of Lamplight Farms, Inc. is requesting registration of a citronella-based mosquito repellent, Cleanburn, containing an unregistered source of active ingredient, Citronella oil, corresponding to the commercial variety "Java," extracted from *Cymbopogon winterianus*. The registrant is fulfilling product chemistry data requirements for the unregistered active ingredient in Cleanburn with data previously submitted for registration of Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3). The source for the oil of citronella in Monarch 1101A and Clearburn is identical. The source of Citronella in Cleanburn remains unchanged from the time of the original registration of Monarch 1101A, and thus the registrant is bridging to MRIDs 486497-01, 486497-03, and 417857-03 respectively, for Manufacturing process of the active ingredient, Citronella oil, Discussion on formation of impurities; Enforcement analytical method that was employed for quantification of Citronella oil present in Monarch 1101A, and Physical/Chemical characteristics of Citronella oil Technical. The registrant references MRID 486497-02 in MRID 503898-02 for Preliminary Analysis of Citronella oil that was conducted for registration of Monarch 1101A.

Data on Product Identity & Composition, Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for End-Use product, Cleanburn, is provided in MRID 503898-01. Data on Physical/Chemical Characteristics of end-use product, Cleanburn, is provided in MRID 503898-03.

Tier I acute mammalian toxicity for the end-use product, Cleanburn, has been addressed with data in MRID 503898-05 for Acute oral; MRID 503898-06 for Acute eye irritation, and MRID 503898-07 for Acute dermal irritation.

Tier I acute mammalian toxicity for the active ingredient, Citronella oil, has been addressed by bridging to MRID 431794-01 for Acute oral; MRID 431671-01 for Acute dermal; MRID 431671-02 for acute inhalation; MRID 431671-03 for Acute eye irritation; MRID 431671-04 for Acute dermal irritation, and MRID 431671-05 for Skin sensitization. These toxicity studies correspond to Citronella oil, commercial variety "Java."

Tier I subchronic mammalian toxicity data, required for the active ingredient supplied from unregistered source, have been addressed with rationale in MRID 503898-11 for waiving further studies. MRID 503898-11 references mutagenicity data in MRIDs 417857-01 and 417857-02, and Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105) with references therein.

Non-target organisms' data requirements are addressed by bridging to data on Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*), A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*), and A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*) in MRIDs 417474-09, 417474-10, and MRID 417474-11, respectively.

Required data on Non-target plants and non-target insects, OCSPP 850.4000 and OCSPP 850.3020, respectively, is waived based on minimal exposure to plants and insects given the use pattern of the product, and the repellent effect of citronella oil on insects.

Lastly, product performance data is addressed by the cite all method. In addition, this submission includes copies of product label, CSF for basic and alternate formulations, dated 2/06/2018, and updated data matrix to address deficiencies identified by the Agency in an Agency's deficiency letter, dated on January 29, 2018.

BACKGROUND INFORMATION

The proposed product, Cleanburn, contains 3% w/w Citronella oil, corresponding to the commercial variety "Java," extracted from *Cymbopogon winterianus*. The source and percent concentration of the active ingredient, Citronella oil (Java variety), present in both, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3) and proposed product, Cleanburn, are identical. Thus, the registrant is bridging to product chemistry data submitted for registration of Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3) to satisfy product chemistry data requirements for Citronella oil in Cleanburn that is supplied by same unregistered supplier and present at the same concentration as in referenced product, Tiki Insect Repellent Monarch 1101A (EPA Reg. No. 33025-3). Cleanburn is a torch fuel formulation to be used outdoors as space repellent against mosquitoes. Label use directions instruct users to pour the content from the original container into vessel, canister or burner and wipe away any excess before lighting. The label doesn't specify space of effective repellency covered by one canister, or how many burning canisters are needed for effective coverture of a given space.

RECOMMENDATIONS AND CONCLUSIONS

Product chemistry:

- 1 The registrant has adequately addressed product chemistry data requirements for end-use product, Cleanburn, and its active ingredient, Citronella oil, **except for the following deficiencies concerning Physical/Chemical characteristics of the active ingredient.** These data are bridged from MRID 417857-03 (Refer to Table 1). Referenced MRID 417857-03 doesn't provide methods for determination of Stability, Storage stability and corrosion characteristics, flammability, relative density or specific gravity, and vapor pressure. MRID 417857-03 doesn't provide quantifiable measurement of PH, visible light absorption, viscosity, boiling point, partition coefficient, and water solubility. These deficiencies listed below, should be resolved:
 - 1a) The registrant needs to **report the methods employed for determination of the following physical/chemical characteristics** for Citronella oil:
 - OCSPP 830.6313 Stability to normal and elevated temperatures, metals and metal ions;
 - OCSPP 830.6315 Flammability;
 - OCSPP 830.6317 Storage Stability
 - OCSPP 830.6320 Corrosion characteristics

OCSPP 830.7300 Density/Relative Density/Bulk Density, and
OCSPP 830.7950 Vapor pressure.

1b) **Measurable numerical values and method of determination are needed** for these physical/chemical characteristics of Citronella oil:

OCSPP 830.7000 pH;
OCSPP 830.7050 UV/ Visible light absorption;
OCSPP 830.7100 Viscosity;
OCSPP 830.7220 Boiling point;
OCSPP 830. 7550, 830.7560, and OCSPP 830.7570 Partition Coefficient (n-Octanol/water), and
OCSPP 830.7840 Water solubility.

- 2 Manufacturing process of Cleanburn is described in MRID 503898-01. However, **quantity of each ingredient used in the formulation of the product is not reported, and it should be reported, together with description of packaging material. Please, upgrade MRID 503898-01 by reporting amount of each component added to the formulation during production process, and describe packaging and packaging material.**

Classification of submitted studies for product chemistry:

Cited MRID 486497-01, Manufacturing process of the active ingredient, Citronella oil, and Discussion on formation of impurities is acceptable. (Refer to Confidential Appendix for details).

MRID 503898-02, bridging to MRID 486497-02 for Preliminary Analysis of Citronella oil, is acceptable. (Refer to Confidential Appendix for details).

Cited MRID 486497-03, is acceptable. Enforcement analytical method employed for quantification of Citronella oil present in Monarch 1101A, containing 3% w/w Citronella oil from same unregistered source as Cleanburn, is suitable for quantification of Citronella oil content in Cleanburn. Citronella oil is present at same concentration in both products, and it is supplied from same unregistered source.

MRID 503898-01, Product Identity & Composition, Formulation Process, Discussion of Formation of Impurities, Certified Limits, and Enforcement Analytical Method for End-Use product, Cleanburn, is **acceptable, pending revision of the manufacturing process. Steps followed during manufacturing process are described on pg. 22 and 23 in MRID 503898-01. However, quantity of each ingredient used in the formulation of the product is not specified, and it should be reported, together with information on packaging material.** This volume also addresses product identity and composition of the active ingredient, Citronella oil. Refer to Confidential Appendix for details on product composition, manufacturing process and analytical methods.

Cited MRID 417857-03, Physical Chemical Characteristics of Citronella oil are **unacceptable**. **The registrant needs to provide data for some of the physical/chemical data requirements that have not been properly addressed neither with applicable rationale nor with numerical values. For example, neither method of determination nor numerical measurement are provided for the following data: OCSPP 830.7000 pH; OCSPP 7050 UV/Visible light absorption; OCSPP 830.7100 Viscosity; OCSPP 830.7220 Boiling point; OCSPP 830.7550, OCSPP 830.7560, and OCSPP 830.7570 Partition Coefficient (n-Octanol/water), and OCSPP 830.7840 Water solubility. In addition, methods employed for determination of the following physical/chemical characteristics of Citronella oil need to be reported: OCSPP 830.6317 Storage Stability and OCSPP 830.6320 Corrosion characteristics; OCSPP 830.6313 Stability to normal and elevated temperatures, metals and metal ions; OCSPP 830.6315 Flammability; OCSPP 830.7300 Density/Relative Density/Bulk Density; OCSPP 830.7950 Vapor pressure.** (Refer to Table 1, and to item # 1 and # 2 in list of deficiencies, above). Cited MRID 417857-03 doesn't provide this information.

MRID 503898-03, Physical/Chemical Characteristics of End-Use product, Cleanburn, is acceptable (Refer to Table 2).

Refer to Tables 1 and 2 for Physical Chemical Characteristics of Citronella oil and Cleanburn product, respectively.

Acute Mammalian Toxicity

Tier I Acute mammalian toxicity data for Citronella oil is acceptable. These data requirements have been adequately addressed by bridging to MRID 431794-01 for Acute oral; MRID 431671-01 for Acute dermal; MRID 431671-02 for acute inhalation; MRID 431671-03 for Acute eye irritation; MRID 431671-04 for Acute dermal irritation, and MRID 431671-05 for Skin sensitization. These cited studies correspond to Citronella oil, commercial variety "Java." Citronella oil is categorized under toxicity category III for acute oral, acute dermal toxicity, acute eye irritation, and acute dermal irritation, and under toxicity category IV for acute inhalation and skin sensitization.

Tier I Acute mammalian toxicity data for end-use product, Cleanburn, has been adequately addressed with data in MRID 503898-05 for acute oral; MRID 503898-06 for acute eye irritation, and MRID 503898-07 for acute dermal irritation.

MRIDs 503898-05, 503898-06 and 503898-07 for Acute oral, Acute Eye irritation, and Acute dermal irritation, respectively, are acceptable.

MRID 503898-11, Study waiver request for Acute dermal, Acute inhalation, and Skin sensitization is acceptable. The registrant's rationale is based on the composition of the formulation (Refer to Confidential Appendix for product composition), use pattern (not for intentional application to human skin), and low toxicity profile of Citronella oil (toxicity category III for acute dermal, and toxicity category IV for acute inhalation and skin sensitization).

MRIDs 505214-01 thru 505214-05 are acceptable. These MRIDs cite Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), with referenced MRID studies therein, in support for waiving Tier I subchronic toxicity studies.

MRID 505214-01 Waiver request for immunotoxicity studies is supported by referenced data in MRIDs 417857-01, and 417857-02. Data in these studies show that Citronella oil is not mutagenic.

MRID 505214-02, Rationale in support of waiving 90-day oral study is based on the use pattern of Cleanburn that will be used as torch fuel. Therefore, oral exposure is not anticipated.

MRID 505214-03 Rationale in support of waiving 90-day dermal study is based on the use pattern of Cleanburn that will be used as torch fuel. Therefore, intentional or prolonged exposure to the product from application to human skin is unlikely.

MRIDs 505214-04 and 505214-05, Request for waiving 90-day Inhalation and Developmental toxicity studies, respectively, is based on Reregistration Eligibility Decision for Oil of Citronella (CASE 3105). These data requirements have been waived in the Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), based on the low toxicity profile of Citronella oil (Commercial variety "Java," which is slightly toxic).

Non-target organisms:

MRID 417474-09, Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*) is acceptable.

Data on required Avian subacute dietary toxicity study, OSCPP 850.2200, is waived based on low acute oral toxicity. Oil of citronella is classified as Non-toxic to birds via the oral route. Furthermore, based on its use pattern, ingestion of the proposed product by birds is not expected.

MRID 417474-10, A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*) is acceptable. Oil of citronella has been classified as slightly toxic to fresh water fish.

MRID 417474-11, A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*) is acceptable. Oil of citronella has been classified as slightly toxic to aquatic invertebrates.

Required data on Non-target plants and non-target insects, OCSPP 850.4000 and OCSPP 850.3020, respectively, are waived based on minimal exposure to plants and insects given the use pattern of the product, and the repellent effect of citronella oil on insects.

Product performance: Unacceptable.

Product performance data is required and needs to be submitted in support of efficacy claim against mosquitoes on the product label. The registrant is resorting to the "cite all" method to satisfy product performance data requirement, however, no efficacy study has been found

suitable for characterizing efficacy of the proposed product against mosquitoes in the USA. Thus, **efficacy data on the proposed product should be submitted unless the registrant can submit efficacy data from me-too product, Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85). Efficacy data cited from Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85) is not in file with the Agency database. Specifically, product performance data is needed for determination of space of effective repellency covered by one canister, how many burning canisters are needed for effective coverture of a given space, and how to place canisters for optimal coverture of a given space.**

Note to RAL

In addition, the product label should provide the following directions concerning use instructions:

Do not use in windy conditions,
 Do not tip torch as fuel can spill and cause fire.
 Do not use gasoline or other combustible or flammable fluids
 Do not place torch under covered shelter
 Do not do not place torch near pedestrian traffic, wood, clothing or dry vegetation
 Adjust wick height no higher than ¾ inches.
 Keep clothing, hair and face away from flame
 To extinguish flame, place snuffer cap completely over wick until flame is extinguished.

CONCLUSION

Based product use pattern and composition, toxicological profile of oil of citronella, and its non-toxic mode of action, no anticipated adverse effects to human health, nontarget organisms, or the environment are expected from application of the proposed product when used according to label directions. However, no efficacy study on file has been found suitable for characterizing efficacy of the proposed product, Cleanburn, against mosquitoes in the USA. Thus, **efficacy data on the proposed product need to be submitted unless the registrant can submit efficacy data from me-too product, Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85). Efficacy data cited from Cutter Insect Repellent Prometheus (EPA Reg. No. 121-85) is not in file with the Agency database..** Specifically, product performance data should be provided for determination of space of effective repellency covered by one canister, or how many burning canisters are needed for effective coverture of a given space.

STUDY SUMMARY

Product Chemistry:

TABLE 1. Physical and Chemical Properties for Citronella oil

Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	Light amber	Visual observation
830.6303 Physical State	liquid	Visual observation
830.6304 Odor	Floral, grassy	Olfactory
830.6313 Stability	Unstable in the presence of alkali. Unstable in the presence of acids (esterification may take place), many strong inorganic acids can cause decomposition and/or polymerization on prolong exposure to UV light in the presence of air.	Not provided
830.6315 Flammability	170 °C	Not provided
830.6317 Storage Stability	Stable under normal conditions.	Not provided
830.6319 Miscibility	N/A The product is not emulsible liquid to be diluted with petroleum solvents	
830.6320 Corrosion Characteristics	Not corrosive	Method not provided
830.7000 pH	Unknown Not provided	
830.7050 UV/ Visible light absorption	Unaddressed	
830.7100 Viscosity	Unknown.	Not provided
830.7200 Melting point/ melting range	N/A	Not a solid
830.7220 Boiling point	170 °C	Not provided
830.7300 Density/Relative Density/Bulk Density	0.891 – 0.901 g/mL	Not provided

TABLE 1. Physical and Chemical Properties for Citronella oil

Guideline Reference No./Property	Description of Result	Methods
830.7520 Particle size, fiber length, diameter distribution	N/A	N/A water soluble and no fibrous substance
830.7550 830.7560 830.7570 Partition Coefficient (n-Octanol/water)	Doesn't dissociate. No numerical value provided	No method of measurement reported
830.7840 Water solubility	Soluble. No numerical value provided	No method of measurement reported
830.7950 Vapor pressure	There is no vapor pressure measurement available for Oil of Citronella, the values given are for the six constituents present in the greatest amounts: Camphene* 3.0 mm Hg at 20°C (est) Limonene 1.4 mm Hg at 25°C Citronellal 0.23 mm Hg at 20°C Geraniol 0.02 mm Hg at 20°C Citronellol 0.015 mm Hg at 25°C Me-isoeugenol* 0.01 mm Hg at 2QPC	Values marked with a * are estimated, all others have been taken from Flavor & Fragrance Ingredient data Sheets compiled by EMARIFM-FMA.

Data from MRID 417857-03

TABLE 2. Physical and Chemical Properties for Cleanburn (basic and alternate formulations)		
Guideline Reference No./Property	Description of Result	Methods
830.6302 Color	N/A	N/A for EP
830.6303 Physical State	liquid	Visual observation
830.6304 Odor	N/A	N/A for EP
830.6313 Stability	N/A	N/A for EP
830.6315 Flammability	N/A	The product doesn't contain combustible liquids
830.6317 Storage Stability	65% geraniol after 14 days at 54°C ± 2°C.	Chromatographic analysis Geraniol peak area percent indicates percent geraniol in the product
830.6319 Miscibility	N/A	The product is not emulsible liquid to be diluted with petroleum solvents.
830.6320 Corrosion Characteristics	No signs of corrosion were noted on the commercial packing material, polyethylene terephthalate.	Visual inspection
830.7000 pH	5.37	pH meter
830.7100 Viscosity	2.5237 mm ² /s (cSt)	Ubbelohde viscometer
830.7300 Density/Relative Density/Bulk Density	0.8701 g/mL	CCL SOP 10.16 method

Data from MRID 503898-03

B. Acute Mammalian Toxicity

Table 3. Toxicological Profile of End-Use product, Cleanburn, Basic Formulation

MRID	Guideline	Test	Results LD ₅₀ /LC ₅₀	Toxicity Category
503898-05	870.1100	Acute Oral Toxicity	>5000 mg/kg	IV
503898-11	870.1200	Acute Dermal	Waiver	Waiver

MRID	Guideline	Test	Results LD ₅₀ /LC ₅₀	Toxicity Category
		Toxicity		
503898-11	870.1300	Acute Inhalation Toxicity	Waiver	Waiver
503898-06	870.2400	Primary Eye Irritation	Mildly irritating - free of irritation by 72 hours	III
503898-07	870.2500	Primary Dermal Irritation	Slightly irritating to skin	IV
503898-11	870.2600	Skin Sensitization	Waiver	Waiver

Table 4. Toxicological Profile of End-Use product, Cleanburn, Alternate Formulation

MRID	Guideline	Test	Results	Category
50389808	870.1100	Acute Oral Toxicity	>5000 mg/kg	IV
50389811	870.1200	Acute Dermal Toxicity	Waiver	Waiver
50389811	870.1300	Acute Inhalation Toxicity	Waiver	Waiver
50389809	870.2400	Primary Eye Irritation	Minimally irritating - free of irritation by 48 hours	III
50389810	870.2500	Primary Dermal Irritation	Slightly irritating to skin	IV
50389811	870.2600	Skin Sensitization	Waiver	Waiver

MRID 503898-11, Data waiver requests for Acute dermal, Acute inhalation, and Skin sensitization are based on the following rationale specific to each data requirement:

OCSPP 870.1200 Acute Dermal Toxicity:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 2:

"2. Required unless test material is corrosive to skin or has a pH between < 2 or 11.5 >." The pH of Cleanburn is 5.37.

In addition, under conditions of use, Cleanburn is not expected to result in dermal exposure.

OCSPP 870.1300 Acute Inhalation Toxicity:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 3:

"3. Required when the product consists of, or under conditions of use would result in, a respirable material (e.g., gas, volatile substances, or aerosol particulate)...."

Concerning Test Note 3, Cleanburn is a liquid and does not consist of a respirable material, such as a gas, vapor or particulate.

OCSP 870.2600 Skin Sensitization:

Per the Agency's Data Requirements for Biochemical as specified in §158.2050: Biochemical pesticides toxicology data requirements table, Test Note 2 & 4:

"2. *Required unless test material is corrosive to skin or has a pH between < 2 or 11.5 >.*"

"4. *Required if repeated contact to human skin is likely to occur under conditions of use*"

Concerning Test Note 2, the pH of Cleanburn is 5.37.

Concerning Test Note 4, under conditions of use Cleanburn is not expected to result in repeated dermal exposure.

In addition, the battery of acute mammalian toxicity studies already conducted on Citronella oil show that Citronella oil is of low mammalian toxicity, classified under toxicity category III for acute oral, acute dermal, acute eye irritation, and acute dermal irritation, and under toxicity category IV for acute inhalation and skin sensitization.

Table 5. Toxicological Profile of Citronella oil

<u>Study Type/OCSP Guideline</u>	<u>LD₅₀/LC₅₀/Results</u>	<u>Toxicity Category</u>	<u>MRID (Java variety)</u>
Acute Oral Toxicity/OCSP 870.1100	> 4,860 mg/kg	III	431794-01
Acute Dermal Toxicity/OCSP 870.1200	> 2,000 mg/kg	III	431671-01
Acute Inhalation Toxicity/OCSP 870.1300	> 3.1 mg/L	IV	431671-02
Acute Eye Irritation/OCSP 870.2400	Mild irritant	III	431671-03
Acute Dermal Irritation/OCSP 870.2500	slightly irritant.	III	431671-04
Skin Sensitization/OCSP 870.2600	Non- sensitizer	IV	431671-05
Hypersensitivity incidents	None reported		

The following Tier I Subchronic toxicity data are required for the active ingredient Citronella oil from an unregistered source: OCSP 870.3100 90-day oral; OCSP 870.3250 90-day dermal; OCSP 90-day inhalation; OCSP 870.3700 Prenatal development, and mutagenicity studies, OCSP 870.5100 Bacterial reverse mutation test, and OCSP 870.5300 / 870.5375 *In vitro*

mammalian cell assay, The registrant is addressing these data requirements by bridging to data previously submitted for registration of Citronella oil technical (TGAI), and by providing the following rationale in support for waiving further testing:

According to the Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105), These data requirements were previously waived by the Agency for the following reasons:

1. The acute mammalian studies listed on Table 5, showed no significant adverse effects for various routes of exposure (Toxicity Category III for acute oral, dermal toxicity, acute eye irritation, and acute dermal irritation, and toxicity category IV for acute Inhalation and skin sensitization). (Refer to Table 5 for toxicological profile of Citronella oil).
2. The GRAS status of oil of citronella (21 CFR 182.2).
3. No report of hypersensitivity of adverse effects following oral and dermal exposure (which is currently accurate).
4. This rationale was used to develop and support an exemption under Section 25(b).

Specifically, the registrant has submitted MRIDs 505214-01 thru 505214-05 to address each Tier I subchronic toxicity data requirement individually:

MRID 505214-01, Waiver request for immunotoxicity.

The registrant is citing Reregistration Eligibility Decision for Oil of Citronella (CASE 3105), with referenced MRID studies therein, in support for waiving additional immunotoxicity testing. According to the Reregistration Eligibility Decision (RED) for Oil of Citronella (CASE 3105), these data were previously waived by the Agency. Cited mutagenicity studies, Salmonella / mammalian microsome reverse mutation assay in MRIDs 417857-01, and *In vitro* Cytogenetic Assay, measuring chromosomal frequencies in Chinese hamster ovary cells in MRID 417857-02, show that Citronella oil is not mutagenic. No increase in number of histidine revertants per plate with or without S9 (3300 µg/plate/+S9; 1,000 µg/plate/-S9, respectively) were reported in MRID 417857-01, and no chromosomal aberrations frequencies in Chinese hamster ovary with or without S9 (150 µg/plate/+S9; 75.5 µg/plate/-S9, respectively) were observed in MRID 417857-02 study.

MRID 505214-02, Waiver request for 90-day oral study is based on the following rationale:

According to the regulations in 40 CFR §158.2050, a 90-day oral toxicity study is required if the use pattern of the active ingredient is likely to result in repeated oral exposure to humans. Cleanburn will be used as torch fuel. Therefore, it is not expected that there would be any oral exposure.

MRID 505214-03, Waiver request for 90-day dermal toxicity study is based on footnote #7 per 40 CFR §158.2050. According to the regulations in 40 CFR §158.2050, the data is required if the product is purposely applied to human skin. Cleanburn will be used as torch fuel. Therefore,

it is not expected that there will be intentional or prolonged exposure to the product from application to human skin.

MRIDs 505214-04 and 505214-05, 90-day Inhalation and Developmental toxicity, respectively. These data requirements have been waived in the Reregistration Eligibility Decision for Oil of Citronella (CASE 3105) based on the following rationale:

1. The acute mammalian studies listed on Table 5, showed no significant adverse effects by various routes of exposure (Toxicity Category III for acute oral, acute dermal toxicity, acute eye irritation, and acute dermal irritation, and toxicity category IV for acute Inhalation and skin sensitization). (Refer to Table 5 for toxicological profile of Citronella oil).
2. The GRAS status of oil of citronella (21 CFR 182.2).
3. No report of hypersensitivity of adverse effects following oral and dermal exposure (which is currently accurate).
4. This rationale was used to develop and support an exemption under Section 25(b).
5. Immunotoxicity data in referenced studies, MRIDs 417857-01 and 417857-02 show that Citronella oil is not mutagenic.

C. Non-Target Organisms

MRID 417474-09, Acute oral toxicity with Northern Bobwhite Quail (*Colinus virginianus*).

The acute oral LD₅₀ value for Northern bobwhite quail exposed to oil of citronella as a single oral dosage was greater than 2250 mg/kg. The LOAEL was 2,250 mg/kg. The NOAEL was 1,350 mg/kg, based on the reduction in body weight for all birds at 2250 mg/kg. Based on these values, oil of citronella is classified as Non-toxic to birds via the oral route.

MRID 417474-10, A 96-hour static acute toxicity test with Rainbow trout (*Oncorhynchus mykiss*)

The LC₅₀ > 17.3 mg/L is based on nominal concentration of oil of citronella. Oil of citronella has been classified as slightly toxic to fresh water fish.

MRID 417474-11, A 48-hour static acute toxicity test with the Cladoceran (*Daphnia magna*).

The EC₅₀ = 26.4 mg/L at 48 hours with 95% CL (13.0 mg – 36.0 mg oil of citronella). Based on these results, Oil of citronella has been classified as slightly toxic to aquatic invertebrates.

Data on required Avian dietary toxicity study, OSCPP 850.2200, is waived based on low acute oral toxicity. Oil of citronella is classified as Non-toxic to birds via the oral route. Furthermore, based on its use pattern, ingestion of the proposed product by birds is not expected

Data on Non-target plants and non-target insects, OCSPP 850.4000 and 850.3020, respectively, have been waived based on minimal exposure to plants and insects given the use pattern of the product and the repellent effect of citronella oil on insects.

Product Performance: No efficacy study on substantially similar product has been found. Therefore, efficacy studies in file for different, and no substantially similar formulations, are not suitable for characterizing performance of Cleanburn product. Product performance data is required for registration of Cleanburn with a claim of efficacy against mosquitoes.

cc: *Clara Fuentes, RAL Menyon Adams, BPPD Chron File, IHAD/ARS FT, PY-S: 05/15/2018.*

CONFIDENTIAL APPENDIX



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DATA MATRIX

Date September 11, 2017	EPA Reg. No./File Symbol 33025-_____	Page 1 of 2
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product Cleanburn

Ingredient(s): **Citronella Oil (PC code 021901)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
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PRODUCT CHEMISTRY

880.1100	Product Identity & Composition	50389801	Lamplight Farms Inc. (33025)	OWN	
880.1200	Description of starting materials, production & formulation process used to produce product	50389801	Lamplight Farms Inc. (33025)	OWN	
880.1400	Discussion of formation of impurities	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1700	Preliminary Analysis	50389802	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	
830.1750	Certified Limits	50389801	Lamplight Farms Inc. (33025)	OWN	
830.1800	Enforcement Analytical Method	50389801	Lamplight Farms Inc. (33025)	OWN	
		48649702	Lamplight Farms Inc. (33025)	OWN	

Physical/Chemical Properties

830.6302	Color	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6303	Physical State	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6304	Odor	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6315	Flammability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6319	Miscibility	N/A			Footnote 1
830.6317	Storage stability	50389803	Lamplight Farms Inc. (33025)	OWN	
830.6320	Corrosion characteristics	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7000	pH	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7100	Viscosity	50389803	Lamplight Farms Inc. (33025)	OWN	
830.7300	Density/Relative Density	50389803	Lamplight Farms Inc. (33025)	OWN	

TOXICOLOGY

	Acute Toxicity Summary	50389804	Lamplight Farms Inc. (33025)	OWN	
870.1100	Acute Oral Toxicity	50389805	Lamplight Farms Inc. (33025)	OWN	
		50389808	Lamplight Farms Inc. (33025)	OWN	
870.1200	Acute Dermal Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
870.1300	Acute Inhalation Toxicity	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver

Signature : <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date Sept. 11, 2017
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DATA MATRIX

Date September 11, 2017		EPA Reg. No./File Symbol 33025-____		Page 2 of 2	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product Cleanburn			
Ingredient(s): Citronella Oil (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
870.2400	Primary Eye Irritation	50389806 50389809	Lamplight Farms Inc. (33025) Lamplight Farms Inc. (33025)	OWN OWN	
870.2500	Primary Dermal Irritation	50389807 50389810	Lamplight Farms Inc. (33025) Lamplight Farms Inc. (33025)	OWN OWN	
870.2600	Skin Sensitization	50389811	Lamplight Farms Inc. (33025)	OWN	Waiver
EFFICACY					
	Product Performance	CITE-ALL	See-Attached List	PAY	

FOOTNOTES

1. A miscibility study is not applicable since the subject product is not diluted with petroleum distillates.

Signature : 	Name and Title: Georgia Anastasiou Agent for Lamplight Farms, Inc	Date Sept. 11, 2017
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DATA MATRIX FOR ACTIVE INGREDIENT

Date September 11, 2017	EPA Reg. No./File Symbol 33025-XX	Page 1 of 3
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051	Product CLEANBURN	

Ingredient(s): **Oil of citronella (PC code 021901)**

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Product Chemistry					
880.1100	Product Identity & Composition	48649701	Lamplight Farms (33025)		
880.1200	Description of starting materials, production & formulation process used to produce product	48649701	Lamplight Farms (33025)		
880.1400	Discussion of formation of impurities	48649701	Lamplight Farms (33025)		
830.1700	Preliminary analysis	48649702	Lamplight Farms (33025)		
830.1750	Certified Limits	41785703	Candle Corp (009201)	OLD	(1)
830.1800	Enforcement analytical method	48649702	Lamplight Farms (33025)		
830.6302	Color	41785703	Candle Corp (009201)	OLD	(1)
830.6303	Physical State	41785703	Candle Corp (009201)	OLD	(1)
830.6304	Odor	41785703	Candle Corp (009201)	OLD	(1)
830.6313	Stability	41785703	Candle Corp (009201)	OLD	(1)
830.6315	Flammability	41785703	Candle Corp (009201)	OLD	(1)
830.6317	Storage Stability	41785703	Candle Corp (009201)	OLD	(1)
830.6319	Miscibility	41785703	Candle Corp (009201)	OLD	(1)
830.6320	Corrosion Characteristics	41785703	Candle Corp (009201)	OLD	(1)
830.7000	pH	41785703	Candle Corp (009201)	OLD	(1)
830.7100	Viscosity	41785703	Candle Corp (009201)	OLD	(1)
830.7200	Melting point	41785703	Candle Corp (009201)	OLD	(1)
830.7220	Boiling point	41785703	Candle Corp (009201)	OLD	(1)
830.7300	Density	41785703	Candle Corp (009201)	OLD	(1)
830.7520	Particle Size	N/A			(2)
830.7550-830.7570	Partition coefficient	N/A			(3)
830.7840	Water solubility	41785703	Candle Corp (009201)	OLD	(1)
830.7950	Vapor Pressure	41785703	Candle Corp (009201)	OLD	(1)

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date Sept. 11, 2017
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DATA MATRIX FOR ACTIVE INGREDIENT

Date	September 11, 2017	EPA Reg. No./File Symbol	33025-XX	Page 2 of 3
Applicant's/Registrant's Name & Address:	Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051	Product	CLEANBURN	
Ingredient(s):	Oil of citronella (PC code 021901)			
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status

TOXICOLOGY

152B-10	Acute Oral Toxicity	41747402 43179401	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
152B-11	Acute Dermal Toxicity	41747403 43167101	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
152B-12	Acute Inhalation Toxicity	41747404 43167102	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
152B-13	Primary Eye Irritation	41747405 43167103	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
152B-14	Primary Dermal Irritation	41747406 43167104	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
152B-15	Dermal Sensitization	41747407 43167105	Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	(1) (1)
152B-16	Hypersensitivity				Not Applicable
152B-17	Microbial mutagenicity	41786701 41785702 41747408	Citronella Joint Venture (67736) Citronella Joint Venture (67736) Candle Corp (009201)	OLD OLD OLD	(1)
152B-18	Immunotoxicity	-		-	Waived (4)
152B-20	90-Day oral toxicity	-		-	Waived (4)
152B-21	90-Day dermal toxicity	-		-	Waived (4)
152B-23	Developmental Toxicity	-		-	Waived (4)

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date Sept. 11, 2017
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DATA MATRIX FOR ACTIVE INGREDIENT

Date September 11, 2017		EPA Reg. No./File Symbol 33025-XX		Page 2 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	
			Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	
			Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	
			Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	
			Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	
			Candle Corp (009201) Citronella Joint Venture (67736)	OLD OLD	
			Citronella Joint Venture (67736) Citronella Joint Venture (67736) Candle Corp (009201)	OLD OLD OLD	
				-	
				-	
				-	
				-	

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date Sept. 11, 2017
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DATA MATRIX FOR ACTIVE INGREDIENT

Date	September 11, 2017	EPA Reg. No./File Symbol	33025-XX	Page 3 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
			Candle Corp (009201)	OLD	(1)
				-	Waived (4)
			Candle Corp (009201)	OLD	(1)
			Candle Corp (009201)	OLD	(1)
					Waived (4)
				-	Waived (4)
				-	Waived (4)

Signature

Georgia Anastasiou

Name and Title:

Georgia Anastasiou, Agent for Lamplight Farms Inc.

Date

Sept. 11, 2017



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

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DATA MATRIX FOR ACTIVE INGREDIENT

Date September 11, 2017		EPA Reg. No./File Symbol 33025-XX		Page 3 of 3	
Applicant's/Registrant's Name & Address: Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051		Product CLEANBURN			
Ingredient(s): Oil of citronella (PC code 021901)					
Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
ECOLOGICAL EFFECTS					
154B-6	Acute Avian Oral	41747409	Candle Corp (009201)	OLD	(1)
154B-7	Avian Subacute Dietary Toxicity	-		-	Waived (4)
154B-8	Fish toxicity	41747410	Candle Corp (009201)	OLD	(1)
154B-9	Invertebrate Toxicity	41747411	Candle Corp (009201)	OLD	(1)
154B-10	Nontarget plants	-			Waived (4)
154B-11	Nontarget insects	-		-	Waived (4)
ENVIRONMENTAL FATE					
	ALL	-		-	Waived (4)

FOOTNOTES

1. Per pages 27-28 of the Oil of Citronella RED, these generic data requirements have been fulfilled.
2. The dissociation constant data requirement is not applicable since citronella does not have any dissociable groups.
3. The partition coefficient data requirement is not applicable since citronella is not a non-polar organic substance.
4. Per pages 28-29 of the Oil of Citronella RED, these generic data requirements have been waived.

Signature <i>Georgia Anastasiou</i>	Name and Title: Georgia Anastasiou, Agent for Lamplight Farms Inc.	Date Sept. 11, 2017
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XBPPD New Product/Registered AI

90 Day Technical Screen

Date: 12/21/2017

Review Date: 12/21/2017

File Symbol No.: 33025-A

Reviewers: Clara Fuentes (Science reviewer)

BPB/MPB: RAB

Comments: Action Code B673. New EP with unregistered source of a.i.

Pass/Fail: Fail for lack of separate rationales addressing each individual data waiver request.

Hours Worked: 8 hours (Clara)

Checklist Item	Yes	No	NA	Comments
1. Forms				
a. 8570-1: Application for Registration	x			
b. 8570-4: CSF	x			
c. 8570-27: Formulator's Exemption			x	
d. 8570-34: Certification with Respect to Data	x			
e. 8570-35: Data Matrix Are any of the data that you are citing compensable? Has an Offer To Pay been made? Is documentation of said offer included in this application (Refer to 40 CFR 152.86 Cite All Method and/or 152.90 Selective Method)?	x			Own data and cite-all, selective method
2. Confidential Statement of Formula (CSF)-review for alternate formulations too				
a. Signed and dated	X			
b. Food-use? (If no, skip to 1e.)		x		
c. All inerts cleared for food-use			x	
d. Active cleared for food-use			x	
e. All inerts cleared for nonfood-use (skip if food-use)	x			180.910

f.	Does the formulation contain an active ingredient that is not a biochemical (conventional or antimicrobial actives)?		x		
g.	CSF accurately reflects label		x		Discrepancy between label and CSF concerning concentration of a.i. and name of active ingredient.
h.	Active(s) + Inert(s) = 100%	x			
i.	CAS #s for all inerts	x			
j.	Chemical names provided for inerts (must list name of impurity)	x			
k.	Units in all applicable boxes	X			
l.	Proprietary inerts? If so, is info. on file with the Agency?		x		
m.	Supplier information adequately listed	X			
n.	Certified limits correct?	X			
o.	If certified limits are outside recommended range, explanation provided?			n/a	
p.	Microbial: culture collection reference			n/a	
q.	Microbial: strain designation for a.i.			n/a	
r.	Microbial: potency provided with a.i.			n/a	
s.	Alternate formulations?	x			
t.	Are alternate formulations actually alternate and not a new product?	x			
u.	Is Reg. No. of source of AI on CSF?		x		Unregistered source
3.	Data Matrix-MP or EP				
a.	Separate data matrix for the product If the study(ies) listed states "conditionally required" (CR), read the data table's footnotes to determine if is required.	X			
b.	All product chemistry/product analysis data requirements addressed (guideline by guideline; Refer to Prod Chem data table 40 CFR 158.2030).	x			

c.	All mammalian/human health toxicology/ pathogenicity data requirements addressed (guideline by guideline; Refer to Human Health data table 40 CFR 158.2050).		x		No rationale is provided addressing each individual guideline for Tier I subchronic data requirement. The registrant addresses these data requirements making reference to pages 28 thru 29 of EPA Citronella RED.
d.	All Tier 1 nontarget organism toxicology/ pathogenicity data requirements addressed (guideline by guideline; Refer to Nontarget data table 40 CFR 158.2060).		x		Non-target organisms' data are addressed with reference to old data, MRIDs 41747409 thru 41747411, and to pages 27 thru 29 in EPA Citronella RED .
e.	Efficacy data must be submitted and included on the data matrix for the EP if claims are being made for public health pests on the product's label.	x			Cite-all, selective method.
f.	HSRB review required?		x		
4.	Data Requirements Guideline Studies				
Note: This section is for submitted guideline studies only. See below for waivers and rationales.					
a.	<p>Product chemistry: do all submitted studies appear to satisfy the data requirements (all impurities over 0.1% must be identified and it must be stated that they are not of toxicological concern)? (Refer to Prod Chem data table 40 CFR 158.2030)</p> <p>Some of the common examples (but not all) of deficiencies which prevent the submission form being forwarded for review are:</p> <p>Product chemistry data requirement is was not addressed.</p> <p>Submitted product chemistry data does not adequately address the data requirement.</p> <p>CSF not correctly filled out.</p> <p>CSF is missing information</p> <p>Information on CSF does not match product chem data.</p>	x			

b.	<p>Toxicology: do all submitted studies appear to satisfy the data requirements? (Refer to Human Health data table 40 CFR 158.2050)</p> <p>Some of the common examples (but not all) of deficiencies which prevent the submission form being forwarded for review are:</p> <p>Data requirement was not addressed.</p> <p>Inadequate argument for bridging data to the pending product.</p> <p>Inadequate rationale submitted to address the data requirement.</p>	x			<p>Own data in addition to data bridged from substantially similar product EPA Reg. No. 33025-3 to satisfy Tier I acute toxicity testing.</p> <p>No rationale is provided addressing each individual guideline for Tier I Subchronic Toxicity data requirement. The registrant addresses all these data requirements making reference to pages 28 thru 29 of EPA Citronella RED</p>
c.	<p>Nontargets: do all the submitted studies appear to satisfy the data requirements? (Refer to Nontarget data table 40 CFR 158.2060)</p> <p>Some of the common examples (but not all) of deficiencies which prevent the submission form being forwarded for review are:</p> <p>Data requirement s was not addressed.</p> <p>Inadequate argument for bridging data to the pending product.</p> <p>Inadequate rationale submitted to address the data requirement.</p>		x		<p>Not individually addressed. No rationale is provided addressing each individual guideline for non-target organisms' data requirement. The registrant addresses all these data requirements generically by making reference to pages 27 thru 28 of EPA Citronella RED</p>

d.	Other (residue data, special studies, etc.) If your product is labeled for public health pests (PR Notice 2002-1 lists public health pests) product performance (efficacy) data requirements must be addressed and submitted. (refer to 40 CFR 158.2070)			x	
5.	Data Requirements-Waivers				
Note: This section is for waivers only. This does not apply to rationale submitted to satisfy the data requirements.					
a.	Are you requesting that you be waived (exempt/excused) from conducting any of the required studies for product chemistry, human health assessment (toxicology) or non-target organisms? If so, have you indicated such with a valid satisfactory reason as to why you should be excused from conducting this study or studies? A common example (but not all) which prevent the submission from being forwarded for review for is that an inadequate reason for the waiver request.	x			Toxicology and Non-targets. Data waiver is requested for Tier I Subchronic toxicity and non-targets, but no separate rationale addressing each individual guideline is submitted.
b.	For each applicable data requirement, does the waiver request have a separate scientific rationale justifying why testing is not applicable and does this rationale appear to be valid enough such that the package can be forwarded for review?		x		Separate rationale requesting to waive each applicable study requirement needs to be submitted for Tier I subchronic toxicity and Non-target organisms.

c.	<p>Does each waiver request seem reasonable and justified?</p> <p>Some common examples (but not all) which prevent the submission form being forwarded for review for :</p> <p>The reason for the waiver request is inadequate.</p> <p>The product and/or a.i is 25(b) or GRAS.</p> <p>The applicant indicated data were waived in the past but no record could be found or past data waiver is not appropriate to the pending product pending product (ex: formulation (solid, gas, liquid) use site, target pest, etc.)</p>		x		Each guideline needs to be individually addressed with separate rationale.
6. Data Requirements - Rationales/Literature					
Note: This section is for rationales only. This does not apply to requests submitted to waive the data requirements.					
a.	Have rationales been submitted in lieu of guideline studies? Please note.		x		Not for each individual guideline
b..	Does each rationale have scientific literature citations where applicable?		x		Only reference to EPA Citronella RED with references therein
c.	Are the rationale and scientific citations organized in reasonable order to facilitate timely review and is each guideline addressed individually?		x		

m.	Storage and disposal	x			
o.	Warranty statement		x		
p.	Worker protection			x	
q.	Batch code	x			

Please use this template below when detailing deficiencies (or similarity issue for similarity screen) found in the technical screen. This is to be included in the checklist

EPA File symbol: 33025-A

Similarity Issue or Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed
<p>Discrepancy between label and CSF concerning concentration of a.i. and name of active ingredient.</p> <p>Study waiver requests for Subchronic Mammalian Toxicity data requirement as set forth in 40 CFR § 158.2050 are not individually addressed, guideline by guideline.</p>	Product label and CSF.	<p>The active ingredient name on product label is "Oil of Citronella". The active ingredient is listed on the CSF as Citronella oil.</p> <p>The concentration of active ingredient listed on product label is 3%. The concentration of active ingredient listed on the CSF is 3.0%</p> <p>No study waiver rationale is provided addressing each individual guideline for the following Tier I Subchronic Toxicity data requirements: 90-day oral (OCSPP870.3100) 90-day dermal (OCSPP(870.3250) 90-day inhalation (OCSPP 870.3465) Prenatal development (OCSPP 870.3700), and <i>In vitro</i> mammalian cell assay (OCSPP 870.5300/ 870.5375). The registrant addresses all these data requirements making reference to pages 28 thru 29 of EPA Citronella RED</p>	<p>The CSF and label need to be amended concerning the name and concentration of active ingredient. Both, name and concentration of active ingredient need to be consistent between label and CSF.</p> <p>Separate MRIDs with specific rationales need to be submitted justifying to waive testing on the following Tier I Subchronic studies: 90-day oral (OCSPP870.3100) 90-day dermal (OCSPP(870.3250) 90-day inhalation (OCSPP 870.3465) Prenatal development (OCSPP 870.3700), and <i>In vitro</i> mammalian cell assay (OCSPP 870.5300/ 870.5375).</p>

Similarity Issue or Deficiency	Data/Information Submitted	Reason for Inadequacies	What Data/Information are Needed?
Study waiver request for Non-target data requirements as set forth in 40 CFR § 158.2060 are not individually addressed, guideline by guideline.	MIRDS 417474-09 thru 417474-11 are cited to address data requirements: Avian Acute Oral (OCSPP 850.2100), and aquatic organisms testing, Fresh water fish acute toxicity (OCSPP 850.1075), and aquatic invertebrate acute toxicity, freshwater (OCSPP 850.1010)	The registrant addresses all these data requirements generically by making reference to pages 27 thru 28 of EPA Citronella RED: Avian Dietary Toxicity (OCSPP 850.2200) Seedling emergence (OCSPP 850.4100) Vegetative vigor (OCSPP 850.4150) Non-target insect (OCSPP 880.4350)	Separate MRIDs with specific rationales need to be submitted justifying to waive testing on: Avian Dietary Toxicity (OCSPP 850.2200) Seedling emergence (OCSPP 850.4100) Vegetative vigor (OCSPP 850.4150) Non-target insect (OCSPP 880.4350)

Listed Data Requirements for product Chemistry

880.1100	Product identity and composition
880.1200	Description of starting materials, production and formulation process
880.1400	Discussion of formation of impurities
830.1700	Preliminary Analysis
830.1750	Certified limits
830.1800	Enforcement Analytical methods
830.6302	Color
830.6303	Physical state
830.6304	Odor
830.6313	Stability to normal and elevated temperatures, metals and metal ions
830.6315	Flammability
830.6317	Storage stability
830.6319	Miscibility

830.6320	Corrosion characteristics
830.7000	pH
830.7050	UV/Visible light absorption
830.7100	Viscosity
830.7200	Melting point
830.7220	Boiling point/boiling range
830.7300	Density/relative density/bulk density
830.7520	Particle size, fiber length, and diameter distribution
830.7550; 830.7560; 830.7570	Partition coefficient (n-Octanol /Water)
830.7840	Water solubility
830.7950	Vapor pressure

Tier I Acute and Subchronic Mammalian Toxicity Data Requirements

870.3100	90-day oral (one species)
870.3250	90-day dermal - rat
870.3465	90-day inhalation – rat
870.3700	Prenatal developmental - rat preferably
870.5100	Bacterial reverse mutation test
870.5300; 870.5375	In vitro mammalian cell assay

Non-Target Organisms Data Requirements

850.2100	Avian Acute Oral
850.2200	Avian Dietary Toxicity
850.1075	Fish acute toxicity, fresh water
850.1010	Aquatic invertebrate acute toxicity, freshwater
850.4100	Terrestrial plant Toxicity: seedling emergence
850.4150	Terrestrial Plant Toxicity: vegetative vigor
880.4350	Non-target insect

PRODUCT CHEMISTRY, TOXICITY, AND NON-TARGET ORGANISM DATA REQUIREMENT CHECKLIST FOR TECHNICAL SCREENS.

THIS LIST IS TO BE USED FOR THE TECH SCREEN BY THE SCIENCE REVIEWER TO MAKE SURE ALL THE DATA REQUIREMENTS HAVE BEEN ADDRESSED. A CHECKLIST IS TO BE USED TO EACH END-USE PRODUCT AND/OR MANUFACTURING USE PRODUCT/TGAI. ALSO NOTE THAT THIS CHECKLIST DOES NOT TAKE INTO ACCOUNT PRODUCT

EPA FILE SYMBOL: 33025-A

PRODUCT NAME: CLEANBURN

PRIA CODE: B673

EP OR MP: EP

DATE: 12/27/2017 CLARA FUENTES

TABLE—BIOCHEMICAL PESTICIDES PRODUCT CHEMISTRY DATA REQUIREMENTS

Guideline Number	Data Requirement	All Use Patterns	Test Substance		Test Notes	Was data addressed (MRID, citation) and how was it addressed (data, rationale, bridging)? If not addressed or inadequate why?
			MP	EP		MRIDs listed in Data Matrix
Product Identity and Composition						
880.1100	Product identity and composition	R	TGAI, MP	TGAI, EP	1, 2	MRID 503898-01
880.1200	Description of starting materials, production and formulation process	R	TGAI, MP	TGAI, EP	2, 3	MRID 503898-01
880.1400	Discussion of formation of impurities	R	TGAI and MP	TGAI and EP	4	MRID 503898-01
Analysis and Certified Limits						

830.1700	Preliminary Analysis	CR	TGAI and MP	TGAI and EP	5, 8	MRID 503898-02
830.1750	Certified limits	R	MP	EP	6	503898-01
830.1800	Enforcement Analytical methods	R	MP	EP	7	503898-01
Physical and Chemical Characteristics						
830.6302	Color	R	TGAI	TGAI	8	503898-03
830.6303	Physical state	R	TGAI and MP	TGAI and EP	8	503898-03
830.6304	Odor	R	TGAI	TGAI	8	503898-03
830.6313	Stability to normal and elevated temperatures, metals and metal ions	R	TGAI	TGAI	8, 17	503898-03
830.6315	Flammability	CR	MP	EP	9	503898-03
830.6317	Storage stability	R	MP	EP	--	503898-03
830.6319	Miscibility	CR	MP	EP	10	503898-03
830.6320	Corrosion characteristics	R	MP	EP	--	503898-03
830.7000	pH	CR	TGAI and MP	TGAI and EP	8, 11	503898-03

830.7050	UV/Visible light absorption	R	TGAI	TGAI	--	503898-03
830.7100	Viscosity	CR	MP	EP	12	503898-03
830.7200	Melting point	CR	TGAI	TGAI	8, 13	503898-03
830.7220	Boiling point/boiling range	CR	TGAI	TGAI	8, 14	503898-03
830.7300	Density/relative density/bulk density	R	TGAI and MP	TGAI and EP	8, 18	503898-03
830.7520	Particle size, fiber length, and diameter distribution	CR	TGAI	TGAI	8, 15	503898-03
830.7550 830.7560 830.7570	Partition coefficient (n-Octanol /Water)	CR	TGAI	TGAI	16	503898-03
830.7840	Water solubility	R	TGAI	TGAI	8	503898-03
830.7950	Vapor pressure	R	TGAI	TGAI	8, 19	503898-03

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides product chemistry and are referenced in the last column of the table in paragraph (d) of this section.

1. Data must be provided in accordance with §158.320.
2. If the MP and EP are produced by an integrated formulation system (non-registered source), these data are also required on TGAI.
3. Data must be provided in accordance with §§158.325, 158.330, and §158.335.
4. Data must be provided in accordance with §158.340.

5. Data must be provided in accordance with §158.345. Also, required to support the registration of each manufacturing-use product (including registered TGAIs) and end-use products produced by an integrated formulation system. Data on other end-use products would be required on a case-by-case basis.
6. Data must be provided in accordance with §158.350.
7. Data must be provided in accordance with §158.355.
8. If the TGAi cannot be isolated, data are required on the practical equivalent of the TGAi. EP testing may also be appropriate.
9. Required if the product contains combustible liquids.
10. Required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.
11. Required if the test substance is soluble or dispersible in water.
12. Required if the product is a liquid.
13. Required when the technical chemical is a solid at room temperature.
14. Required when the technical chemical is a liquid at room temperature.
15. Required for water insoluble test substances ($>10^{-6}$ g/l) and fibrous test substances with diameter $\geq 0.1 \mu\text{m}$.
16. Required for organic chemicals unless they dissociate in water or are partially or completely soluble in water.
17. Data on the stability to metals and metal ions is required only if the active ingredient is expected to come in contact with either material during storage.
18. True density or specific density are required for all test substances. Data on bulk density is required for MPs or EPs that are solid at room temperature.
19. Not required for salts.

TABLE—BIOCHEMICAL PESTICIDES HUMAN HEALTH ASSESSMENT DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes	Was data addressed (MRID, citation) and how was it addressed (data, rationale, bridging)? If not addressed or inadequate why?
		Food	Nonfood	MP	EP		MRIDs listed in data matrix
Tier I							
Acute Testing							
870.1100	Acute oral toxicity – rat	R	R	TGAI and MP	TGAI and EP	1	503898-05 503898-04
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI and EP	1, 2	503898-11 503898-04
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	3	503898-11 503898-04
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	2	503898-06 503898-04
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 2	503898-07 503898-10 503898-04
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	2, 4	503898-11 503898-04
none	Hypersensitivity incidents	R	R	All	All	5	----

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes	Was data addressed (MRID, citation) and how was it addressed (data, rationale, bridging)? If not addressed or inadequate why?
		Food	Nonfood	MP	EP		MRIDs listed in data matrix
Subchronic Testing							
870.3100	90-day oral (one species)	R	CR	TGAI	TGAI	6	Waiver request
870.3250	90-day dermal - rat	CR	CR	TGAI	TGAI	7	Waiver request
870.3465	90-day inhalation - rat	CR	CR	TGAI	TGAI	8	Waiver request
Developmental Toxicity							
870.3700	Prenatal developmental - rat preferably	R	CR	TGAI	TGAI	9	Waiver request
Mutagenicity Testing							
870.5100	Bacterial reverse mutation test	R	CR	TGAI	TGAI	10	417867-01 417857-02 417474-08
870.5300 870.5375	In vitro mammalian cell assay	R	CR	TGAI	TGAI	10, 11	Waiver request
Tier II							
Mutagenicity Testing (In vivo cytogenetics)							
870.5385 870.5895	In vivo Mammalian Cytogenetics	CR	CR	TGAI	TGAI	13	
Developmental Toxicity							

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes	Was data addressed (MRID, citation) and how was it addressed (data, rationale, bridging)? If not addressed or inadequate why?
		Food	Nonfood	MP	EP		MRIDs listed in data matrix
870.3700	Prenatal developmental	CR	CR	TGAI	TGAI	9	n/a
Special Tests							
880.3550	Immunotoxicity	CR	CR	TGAI	TGAI	12, 13	n/a
Applicator/User Exposure							
875.1100	Dermal outdoor exposure	CR	CR	TGAI	TGAI	15	n/a
875.1200	Dermal indoor exposure	CR	CR	TGAI	TGAI	15	n/a
875.1300	Inhalation outdoor exposure	CR	CR	TGAI	TGAI	15	n/a
875.1400	Inhalation indoor exposure	CR	CR	TGAI	TGAI	15	n/a
875.1500	Biological monitoring	CR	CR	TGAI	TGAI	15	n/a
Tier III							
Chronic Testing/Special Testing							N/A
880.3800	Immune response	CR	CR	TGAI	TGAI	14	n/a
870.3800	Reproduction and fertility effects	CR	CR	TGAI	TGAI	16	n/a
870.4100	Chronic oral - rodent and nonrodent	CR	CR	TGAI	TGAI	17	n/a

Guideline Number	Data Requirement	Use Patterns		Test Substance		Test Notes	Was data addressed (MRID, citation) and how was it addressed (data, rationale, bridging)? If not addressed or inadequate why?
		Food	Nonfood	MP	EP		MRIDs listed in data matrix
870.4200	Carcinogenicity - two species - rat and mouse preferred	CR	CR	TGAI	TGAI	18	n/a
870.5380	Mammalian spermatogonial chromosome aberration test	CR	CR	TGAI	TGAI	19	n/a
Special Testing							N/A
870.7200	Companion animal safety	CR	CR	NR	TGAI or EP	20	n/a

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides human health assessment as referenced in the last column of the table in paragraph (d) of this section.

1. Required unless the test material is a gas or highly volatile (vapor pressure >10⁻⁴ torr (mm/Hg)).
2. Required unless the test material is corrosive to skin or has pH <2 or >11.5.
3. Required when the pesticide, under conditions of use, would result in respirable material (e.g., gas, volatile substance or aerosol/particulate), unless it is a straight chain lepidopteran pheromone.
4. Required if repeated contact with human skin is likely to occur under conditions of use.
5. Hypersensitivity incidents must be reported as adverse effects data.
6. Required for non-food uses that are likely to result in repeated oral exposure to humans.
7. Required to support uses involving purposeful application to the human skin or which would result in comparable prolonged human exposure to the product (e.g., insect repellents) and if any of the following criteria are met:
 - i. Data from a 90-day oral study are not required.

ii. The active ingredient is known or expected to be metabolized differently by the dermal route of exposure than by the oral route and the metabolite is of toxicological concern.

iii. The use pattern is such that the dermal route would be the primary route of exposure.

8. Required if there is a likelihood of significant levels of repeated inhalation exposure to the pesticide as a gas, vapor, or aerosol.

9. Required if the use of the product under widespread and commonly recognized practice may reasonably be expected to result in significant exposure to female humans (e.g., occupational exposure or repeated application of insect repellents directly to the skin). Tier II data is required on a different test species from Tier I data when developmental effects are observed in the first study and information on species-to-species extrapolation is needed.

10. Required to support nonfood uses if either:

i. The use is likely to result in significant human exposure; or

ii. The active ingredient (or its metabolites) is structurally related to a known mutagen or belongs to any chemical class of compounds containing a known mutagen. Additional mutagenicity tests that may have been performed plus a complete reference list must also be submitted. Subsequent testing may be required based on the available evidence.

11. Choice of assay using either:

i. Mouse lymphoma L5178Y cells, thymidine kinase (tk) gene locus, maximizing assay conditions for small colony expression or detection;

ii. Chinese hamster ovary (CHO) or Chinese hamster lung fibroblast (V79) cells, hypoxanthine-guanine phosphoribosyl transferase (hgppt) gene locus, accompanied by an appropriate *in vitro* test for clastogenicity; or

iii. CHO cells strains AS52, xanthine-guanine phosphoribosyl transferase (xppt) gene locus.

12. Required if there are effects on hematology, clinical chemistry, lymphoid organ weights, and histopathology are observed in the 90-day studies.

13. The micronucleus rodent bone marrow assay is preferred; however, rodent bone marrow assays using metaphase analysis (aberrations) are acceptable.

14. Required if adverse effects are observed in the Tier II immunotoxicity study. The protocol for evaluating adverse effects to the immune response should be developed after evaluating the effects noted in the immunotoxicity study.

15. These data are required when the data used for the human health assessment indicates that the biochemical may pose a potential hazard to the applicator/user.

16. Required if there is evidence of:

- i. Endocrinological effects from the subchronic toxicity studies.
- ii. Developmental effects in the prenatal developmental toxicity study(s), or
- iii. Genotoxicity to mammals based on results from the mutagenicity tests.

The use of a combined study that utilizes the two-generation reproduction study in rodents (guideline 870.3800) as a basic protocol for the addition of other endpoints or functional assessments in the immature animal is encouraged.

17. Required if the potential for adverse chronic effects is indicated based on any of the following:

- i. The subchronic effect level established in the following Tier I studies: 90-day oral toxicity study, 90-day dermal toxicity study, or 90-day inhalation toxicity study.
- ii. The pesticide use pattern (e.g., rate, frequency, and site of application).
- iii. The frequency and level of repeated human exposure that is expected.

18. Required if the product meets either of the following criteria:

- i. The active ingredient (or any of its metabolites, degradation products, or impurities) produce(s) in Tier I subchronic studies a morphologic effect (e.g., hyperplasia or metaplasia) in any organ that potentially could lead to neoplastic change.
- ii. Adverse cellular effects suggesting carcinogenic potential are observed in Tier II immunotoxicity and Tier III immune response study or in Tier II mammalian mutagenicity assays.

In addition, a 90-day range finding study in both rats and mice is required to determine the dose levels if carcinogenicity studies are required. If the mouse carcinogenicity study is not required, the 90-day mouse subchronic study is likewise not required.

19. Required if results from lower tiered mutation or reproductive studies indicate there is potential for chromosomal aberration to occur.

20. May be required if the product's use will result in exposure to domestic animals through, but not limited to, direct application or consumption of treated feed.

TABLE—BIOCHEMICAL PESTICIDES NONTARGET ORGANISMS AND ENVIRONMENTAL FATE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Patterns					Test Substance	Test Notes	Was data addressed (MRID, citation) and how was it addressed (data, rationale, bridging)? not addressed or inadequate why?
		Terrestrial	Aquatic	Greenhouse	Forestry, Residential Outdoor	Indoor			
		Food/Feed/Nonfood	Food/Nonfood	Food/Nonfood		Food/Nonfood			
Tier I									
Avian Testing									
850.2100	Avian Acute Oral	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4	417474-09
850.2200	Avian Dietary Toxicity	R	R	CR	R	CR	TGAI, EP	1, 2, 3, 4	Waiver request
Aquatic Organism Testing									
850.1075	Fish acute toxicity, fresh water	R	R	CR	R	CR	TGAI, EP	2, 3, 4, 5	417474-10
850.1010	Aquatic invertebrate acute toxicity, freshwater	R	R	CR	R	CR	TGAI, EP	2, 3, 5	417474-11
Nontarget Plant Testing									
850.4100	Terrestrial plant Toxicity: seedling emergence	R	R	NR	R	NR	TGAI, EP	5	Waiver request

850.4150	Terrestrial Plant Toxicity: vegetative vigor	R	R	NR	R	NR	TGAI, EP	5	Waiver request
Insect Testing									
880.4350	Non-target insect	R	R	R	R	NR	TGAI	14	Waiver request
Tier II									
Environmental Fate Testing									Environmental fate data (concerning soil) should be addressed in support of non-Food Classification request
163-1 (835.1230)	Sediment and soil adsorption/desorption for parent and degradates	CR	CR	CR	CR	NR	TGAI	6	n/a
163-1 (835.1240)	Soil column leaching	CR	CR	CR	CR	NR	TGAI	6	n/a
163-2 (835.1410)	Laboratory volatilization from soil	CR	NR	CR	CR	NR	TEP	7	n/a
161-1 (835.2120)	Hydrolysis	CR	CR	CR	CR	NR	TGAI	6	n/a
161-1 (835.4100)	Aerobic soil metabolism	CR	NR	CR	CR	NR	TGAI	6	n/a
161-2 (835.2240)	Photodegradation in water	CR	CR	CR	CR	NR	TGAI	6	n/a
161-3 (835.2410)	Photodegradation on soil	CR	NR	CR	CR	NR	TGAI	6	n/a
162-2 (835.4200)	Anaerobic soil metabolism	CR	NR	NR	NR	NR	TGAI	6	n/a

162-4 (835.4300)	Aerobic aquatic metabolism	CR	CR	CR	CR	NR	TGAI	6	n/a
162-3 (835.4400)	Anaerobic aquatic metabolism	CR	CR	NR	NR	NR	TGAI	6	n/a
880.4425	Dispenser - water leaching	CR	NR	CR	CR	NR	EP	8	n/a
Nontarget Plant									
850.4225	Seedling emergence	R	R	NR	R	NR	TGAI	9	n/a
850.4250	Vegetative vigor	R	R	NR	R	NR	TGAI	9	n/a
Tier III									
Aquatic Fauna Chronic, Life Cycle, and Field Studies									N/A
850.1300 850.1400 850.1500	Freshwater fish/invertebrate testing	CR	CR	NR	CR	NR	TGAI	10	n/a
850.1025 850.1035 850.1045 850.1055 850.1350 850.1400 850.1500	Marine/Estuarine fish/invertebrate animal testing	CR	CR	NR	CR	NR	TGAI	10	n/a
850.1950	Aquatic field fish/invertebrate testing	CR	CR	NR	CR	NR	EP	10	n/a
Terrestrial Wildlife									N/A
850.2300	Avian Reproduction	CR	CR	NR	CR	NR	TGAI	11	n/a
850.2400	Wild mammal acute toxicity	CR	CR	NR	CR	NR	TGAI	11	n/a

850.2500	Terrestrial field testing	CR	CR	NR	CR	NR	EP	11	n/a
Beneficial Insects									
850.3040	Field testing for Pollinators	CR	CR	NR	CR	NR	TEP	12	n/a
Nontarget Plants									
850.4225 850.4250 850.4300 850.4450	Nontarget plant	CR	CR	NR	CR	NR	TGAI	13	n/a

(e) *Test notes.* The following test notes are applicable to the data requirements for biochemical pesticides nontarget organisms and environmental fate as referenced in the last column of the table contained in paragraph (d) of this section.

1. Required for the EP when any end-use formulation may contain other ingredients that may be toxic to nontarget organisms or to support arthropod pheromones that would be available to avian wildlife, (e.g., a granular product).

2. Tests for pesticides intended solely for indoor application would be required on a case-by-case basis, depending on use pattern, physical/chemical properties, production volume, and other pertinent factors.

3. Not required for any use groups if the pesticide is highly volatile (estimated volatility $>5 \times 10^{-5}$ atm m³/mol).

4. Preferred test species are Upland game, waterfowl, or passerine for avian acute oral toxicity studies; Upland game and waterfowl for avian dietary studies; and coldwater fish species for acute freshwater fish studies.

5. Required for the EP when the end-use formulation may contain other ingredients that may be toxic to nontarget organisms.

6. Required on a case-by-case basis when results from Tier I studies indicate adverse effects.

7. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied on land. In view of methodological difficulties with the study of photodegradation in air, prior consultation with the Agency regarding the protocol is recommended before the test is performed.

8. Required when results of any one or more of the nontarget organism studies in Tier I indicate potential adverse effects on nontarget organisms and the pesticide is to be applied in a passive dispenser.

9. Required to support registration of known phytotoxicants, *i.e.*, herbicides, desiccants, defoliants, and plant growth regulators.
10. Required if environmental fate characteristics indicate that the estimated environmental concentration of the pesticide in the aquatic environment is >0.01 of any EC_{50} or LC_{50} determined in the aquatic nontarget organism testing.
11. Required if either of the following criteria are met:
- i. Environmental fate characteristics indicate that the estimated concentration of the pesticide in the terrestrial environment is >0.20 the avian dietary LC_{50} or equal to >0.20 the avian oral single dose LD_{50} (converted to ppm).
 - ii. The pesticide or any of its metabolites or degradation products are stable in the environment to the extent that potentially toxic amounts may persist in the avian or mammalian feed.
12. Required when results of Tier I nontarget organism studies indicate potential adverse effects on nontarget insects and results of Tier II tests indicate exposure of nontarget insects. Additional insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., threatened or endangered species).
13. Required if the product is expected to be transported from the site of application by air, soil, or water. The extent of movement would be determined by the results of the Tier II environmental fate studies.
14. Required depending on pesticide mode of action, method and timing of application, and results of any available efficacy data. Typically the honeybee acute toxicity guideline (guideline 850.3020) satisfies this requirement, however, additional nontarget insect species may have to be tested if necessary to address issues raised by use patterns and potential exposure of important nontarget insect species, (e.g., endangered species.)

Product Performance, Series OCSPP 810.

Submitted product performance studies in MRID 501202-09 through MRID 501202-13



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 16, 2017

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OPP Decision Number: D-534726
EPA File Symbol or Registration Number: 33025-A
Product Name: Cleanburn
EPA Receipt Date: 06-Oct-2017
EPA Company Number: 33025
Company Name: LAMPLIGHT FARMS, INC.

GEORGIA ANASTASIOU
LEWIS & HARRISON, LLC
AGENT FOR LAMPLIGHT FARMS, INC.
122 C STREET, NW - SUITE 505
WASHINGTON, DC 20001-

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-2011-3 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B673

NEW PRODUCT;MUP OR END USE PRODUCT WITH UNREGISTERED SOURCE OF THE ACTIVE INGREDIENT;CITATION OF TGAI DATA PREVIOUSLY REVIEWED AND ACCEPTED BY THE AGENCY;REQUIRES AN AGENCY DETERMINATION THAT THE CITED DATA SUPPORTS THE NEW PRODUCT;REQUIRES AN AGENCY DETERMINATION THAT THE CITED DATA SUPPORTS THE NEW PRODUCT;

No additional payment is due at this time. If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703)-305-5659.

Sincerely,

A handwritten signature in black ink, appearing to be "J. L. Harrison".

Front End Processing Staff
Information Technology & Resources Management Division



Fee for Service

{1010151r~

This package includes the following

• New Registration

• Amendment

✓ Studies? Fee Waiver?

volpay % Reduction: _____

for Division

• AD

• BPPD

• RD

Risk Mgr.

91

Receipt No.

S-

1010151

EPA File Symbol/Reg. No.

33025-A

Pin-Punch Date:

10/6/2017

☐ This item is NOT subject to FFS action.

Action Code:

Requested:

B673

Granted:

B673

Amount Due: \$ _____

Parent/Child Decisions:

Inert Cleared for Intended Use

Uncleared Inert in Product

Reviewer: Andrew Bryceland

Date: 10/13/17

Remarks:

S 1010151 Milestone Email georgia@lewisharrison.com

Regulatory Type: Product Registration - Section 3

Application Type: New Registration

Company 33025 LAMPLIGHT FARMS INC





Fee For Service ☐ Yes ☒ No
Billable ☒ Yes ☐ No
V

Print Letter
Enter More Information
Tracking

Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product # 33025-A Product Name: Cleanburn

Me Too Section3: Me Too Product Name

Application Date: 13-Sep-2017  OPP Rec'd Date: 06-Oct-2017 
Front End Date: 12-Oct-2017  Risk Manager Send Date 
FFS Due Date: Negotiated Due Date
OPP Target Date:

Receipt Content
Study
CSF
< >

☐ New Ingredient ☐

Receipt Description

View/Edit

Portal submission pkg# 23234 PRIA B673 New registration

☐

☐



Receipt

Your payment is submitted

Pay.gov Tracking ID: 2659FLNV

Agency Tracking ID: 75339780217

Form Name: Pesticide Registration Improvement Act - Prepayment

Application Name: PRIA Service Fees

Payment Information

Payment Type: Bank account (ACH)

Payment Amount: \$5,107.00

Transaction Date: 10/06/2017 06:01:01 PM EDT

Payment Date: 10/10/2017

Registration Number:

Company Name: Lamplight Farms, Inc.

Company Number: 33025

Action Code: B673

Account Information

Account Holder Name: David Lewis


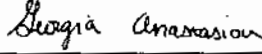
Routing Number: 051400549

Account Number: *****8515

Email Confirmation Receipt

Confirmation Receipts have been emailed to:

georgia@lewisharrison.com

 EPA United States Environmental Protection Agency Washington, DC 20460		<input checked="" type="checkbox"/> Registration <input type="checkbox"/> Amendment <input type="checkbox"/> Other:	OPP Identifier Number
Application for Pesticide - Section I			
1. Company/Product Number 33025-		2. EPA Product Manager Andrew Bryceland	
4. Company/Product (Name) CLEANBURN		3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted	
5. Name and Address of Applicant (Include ZIP Code) Lamplight Farms, Inc. c/o Lewis & Harrison, LLC 122 C ST. NW, Suite 505 Washington, DC 20001		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(I), my product is similar or identical in composition and labeling to: EPA Reg. No. <u>Tiki Insect Repellent Monarch 1101A</u> Product Name: <u>33025-3</u>	
<input type="checkbox"/> Check if this is a new address			
Section - II			
<input type="checkbox"/> Amendment - Explain below. <input type="checkbox"/> Resubmission in response to Agency letter dated _____ <input type="checkbox"/> Notification - Explain below.		<input type="checkbox"/> Final printed labels in response to Agency letter dated _____ <input type="checkbox"/> "Me Too" Application <input checked="" type="checkbox"/> Other - Explain below	
Explanation: Use additional page(s) if necessary. (For Section I and Section II.) <div style="text-align: center;"> New End-Use Product Registration PRIA Category B673, Fee \$5107 Confirmation of Payment Enclosed </div>			
Section - III			
1. Material This Product Will Be Packaged in:			
Child-Resistant Packaging <input type="checkbox"/> Yes* <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Unit Packaging wgt. No. per container	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If "Yes" Package wgt. No. per container	2. Type of Container <input type="checkbox"/> Metal <input checked="" type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify)
*Certification must be submitted			
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container	4. Size(s) Retail Container 2- 128 fl. oz.	5. Location of Label Directions <input checked="" type="checkbox"/> On Label <input type="checkbox"/> On labeling accompanying product	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Other _____ <input checked="" type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			
Section - IV			
1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application)			
Name Georgia Anastasiou, Lewis & Harrison, LLC, 122 C Street NW, Ste. 505, Washington, DC 20001		Title Agent	Telephone No. (Include Area Code) 202-393-3903 x. 119
Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)
2. Signature 		3. Title Agent	
4. Typed Name Georgia Anastasiou		5. Date September 11, 2017	

LEWIS & HARRISON

Consultants in Government Affairs

122 C Street, N.W. Suite 505
Washington, DC 20001
telephone 202.393.3903
fax 202.393.3906

September 13, 2017

E-Submission

Document Processing Desk (REGFEE)
Office of Pesticide Programs (7504P)
US Environmental Protection Agency
Room S-4900, One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202-4501

ATTENTION: **Andrew Bryceland**
 Biopesticides and Pollution Prevention Division

SUBJECT: **Lamplight Farms, Inc.**
 CLEANBURN (33025-__)
 Application to Register End Use Product
 PRIA Category B673

Dear Mr. Bryceland:

On behalf of Lamplight Farms, Inc., I am submitting an application to register the end-use product, CLEANBURN. This product contains 3% citronella oil as the active ingredient and will be used as an outdoor torch fuel to repel flying insects. This product is similar in composition and use to the currently registered product *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3, with the exception of the inert ingredients.

In support of this registration, I am submitting product chemistry data and acute toxicity data. As for efficacy data requirements Lamplight wishes to use the "cite-all" option. Both *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3 and CLEANBURN contain 3% oil of citronella as the active ingredient. As stated above, with the exception of the inert ingredients, which are expected to have no impact on efficacy, this formula is the same as the formula for *Tiki Insect Repellent Monarch 1101A*, EPA Reg. No. 33025-3.

I believe the PRIA Category code for this registration falls under B673 since the source of TGA1 for the citronella oil is the same as *Tiki Insect Repellent Monarch 1101A*.

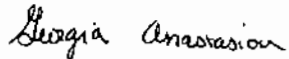
In support of this application, enclosed please find the following documents:

- 1) Application for Pesticide Registration;
- 2) Payment Receipt;
- 3) Propose Product Label;
- 4) Basic and Alternate#1 Confidential Statements of Formula dated 9/11/2017;

- 5) Certification with Respect to Data Compensation;
- 6) End-Use Data Matrix (both Public and Agency copies);
- 7) Generic Data Matrix (both Public and Agency copies);
- 8) Transmittal Document; and,
- 9) Product Chemistry & Acute Toxicity data.

Thank you for in advance for your help with this request. If you have any questions about this submission, please contact me at (202) 393-3903 ext. 19 or by email at georgia@lewisharrison.com.

Sincerely,



Georgia Anastasiou
Agent for,
Lamplight Farms, Inc.

cc: Bill Tobin (Lamplight)
Luke Zeitler (Lamplight)

EPA TRANSMITTAL DOCUMENT

SUBMISSION DATED: September 11, 2017
STUDY SUBMITTER: Lamplight Farms
4900 North Lilly Road
Menomonee Falls, WI 53051
PRODUCT: CLEANBURN
EPA REG. NO.: 33025-
REGULATORY ACTION: PRIA Code B673

STUDIES SUBMITTED:

MRID: 50389801 CLEANBURN: Product Properties (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 9 pages, including 27 page confidential appendix.

MRID: 50389802 CLEANBURN: Preliminary Analysis (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50389803 Physical and Chemical Characteristics of Cleanburn with 3% Citronella: Color, Physical State, Odor, Oxidation/Reduction, Flammability, Storage Stability, Corrosion Characteristics, pH, Viscosity and Relative Density (September 19, 2017) by Brian A. Roe, Case Laboratories; Study No: 4780-06; 14 pages.

MRID: 50389804 CLEANBURN: Summary of Acute Toxicity Data (September 11, 2017) by Georgia Anastasiou, Lewis & Harrison; 4 pages.

MRID: 50389805 CLEANBURN TORCH FUEL WITH 3% CITRONELLA OIL: Acute Oral Toxicity – Up and Down Porcedure in Rats (September 1, 2017) by Carolyn Lowe, Product Safety Labs; Study No: 46226; 14 pages.

MRID: 50389806 CLEANBURN TORCH FUEL WITH 3% CITRONELLA OIL: Primary Eye Irritation in Rabbits (September 1, 2017) by Carolyn Lowe, Product Safety Labs; Study No: 46227; 15 pages.

MRID: 50389807 CLEANBURN TORCH FUEL WITH 3% CITRONELLA OIL: Primary Skin Irritation in Rabbits (September 1, 2017) by Carolyn Lowe, Product Safety Labs; Study No: 46228; 17 pages.

MRID: 50389808 PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL: Acute Oral Toxicity – Up and Down Porcedure in Rats (September 1, 2017) by Melissa Slonina, Product Safety Labs; Study No: 46229; 14 pages.

- MRID: 50389809** **PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL:**
Acute Oral Toxicity – Primary Eye Irritation in Rabbits (September 1,
2017) by Melissa Slonina, Product Safety Labs; Study No: 46230; 17
pages.
- MRID: 50389810** **PALM KERNEL METHLY ESTER WITH 3% CITRONELLA OIL:**
Acute Oral Toxicity – Primary Skin Irritation in Rabbits (September 1,
2017) by Melissa Slonina, Product Safety Labs; Study No: 46231; 17 pages
- MRID: 50389811** **CLEANBURN: Waiver Request for Acute Toxicity Testing** (September
11, 2017) by Georgia Anastasiou, Lewis & Harrison; 5 pages.

COMPANY CONTACT: Georgia Anastasiou
Lewis & Harrison, LLC
123 C Street NW, Suite 505
Washington, DC 20001
(202) 393-3903 x119
georgia@lewisharrison.com


UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

401 M Street, S.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

Certification with Respect to Citation of Data

Applicant's/Registrant's Name, Address and Telephone Number Lamplight Farms Inc, 4900 North Lilly Road, Menomonee Falls, WI 53051	EPA Registration Number/ File Symbol 33025-_____
Active Ingredient(s) and/or representative test compound(s): Citronella Oil (PC code 021901)	Date September 11, 2017
General use pattern(s) (list all those claimed for this product using 40 CFR Part 158) Outdoor non-food	Product Name CLEANBURN

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

- ☐ I am responding to a Data Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

- | | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

- ☒ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data Call-In Notice is supported by all data submitted or cited in the application for registration, the form for reregistration, or this Data Call-In response. In addition, if cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original submitter or that I have obtained the written permission of the original submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the written permission of the original data submitter to use this study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate and complete. I acknowledge that any knowingly false or misleading statements may be punishable by fine or imprisonment or both under applicable law.

Signature <i>Georgia Anastasiou</i>	Date Sept. 11, 2017	Typed or Printed Name and Title Georgia Anastasiou, Agent for Lamplight Farms Inc.
--	-------------------------------	--

PRIA 3 – 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

September 2012

21 Day Screen Start Date: 10-6-17

Experts In-Processing Signature: B.B. Date 10-16-17 Fee Paid: Yes ☒

Division management contacted on issues No ☐ Yes ☐ Date _____

EPA Reg. Number: <u>33025-A</u>		EPA Receipt Date: <u>10-6-17</u>					
Items for Review					Yes	No	N/A*
1	Application Form (EPA Form 8570-1) signed & complete including package type				X		
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)				X		
	a) All <u>inerts</u> , including fragrances, approved for the proposed uses (see Footnote A)	yes	no				
		X					
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)				X		
	Certificate and data matrix consistent				X		
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no				
	If applicable, is there a letter of Authorization for exclusive use only.						
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)						X
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack)				X		
5	a) Selective Method (Fee category experts use)	yes	no				
		X					
	b) Cite-All (Fee category experts use)						
	c) Applicant owns all data (Fee category experts use)						
6	5 Copies of Label (Electronic labels on CD are encouraged and guidance is available)				X		
7	Is the data package consistent with PR Notice 86-5				X		
8	Notice of Filing included with petitions						X

9	If applicable for conventional applications, <u>reduced risk rationale</u>			X
10	<u>Required Data</u> and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

* Documentation: (Pass) / Fail

- Required forms are complete

* Intent: (Pass) / Fail

- Intent approved for Non-Food use

* PRN 113: (Pass) / Fail

MRZD: 503898

- 503898(02) - no Confidential Attachment when Confidential is claimed

- contacted the submitter on 10-17-17

- received the correction on 10-18-17

* Overall Status: (Pass) / Fail

DL 10-18-17

* N/A – Not Applicable

Footnotes

A. During the 21 day initial content review, all CSFs will be reviewed to determine whether all inerts listed, including fragrances, are approved for the proposed uses or have an application pending with the Agency. If an unapproved inert with no application pending with the Agency is identified, the applicant must either 1) resolve the inert issue by, for example, removing the inert, substituting it with an approved inert, submitting documentation that EPA approved the inert for the proposed pesticidal uses, correcting mistakes on the CSF, etc. or 2) provide the data to support OPP approval of the inert or 3) withdraw the application. Removing or substituting an inert ingredient will require a new CSF and may require submission of data. All information, forms, data and documentation resolving the inert issue must have been received by the Agency or the application withdrawn within the 21 day period, otherwise, the Agency will reject the application as described below.

To successfully complete this aspect of the 21 day initial content screen, applicants are **strongly encouraged** to verify that all inert ingredients have been approved for the application's uses or have an application pending with the Agency **even if a product is currently registered** by consulting the [inert Web site](#) and if the inert is not approved nor has an application pending with the Agency, to **obtain the necessary inert approval prior to submitting an application to register a pesticide product containing that inert ingredient**. Some inert ingredients are no longer approved for food uses or certain types of uses. The name and/or CAS number on a CSF must match the name and CAS number on this web site. Simple typographical errors in the name or CAS number have resulted in processing delays.

If an inert is not listed on the inert ingredient web site and the applicant believes that the inert has been approved, the applicant should contact the Inert Ingredient Assessment Branch (IIAB) at inertsbranch@epa.gov and resolve the issue. Copies of the correspondence with IIAB resolving the issue should accompany the application. All new inerts except PIP inerts are reviewed by IIAB. The IIAB should also be contacted for any questions on what supporting data needs to be submitted for and the Agency's inert review process. Questions on PIP inerts should be directed to the [Chief of Microbial Pesticides Branch](#).

When a brand, trade, or proprietary name of an inert ingredient is listed on a CSF, additional information such as an alternate name of the inert, CAS number or other information must also be included to enable the Agency to determine if it has been approved. Each component of an inert mixture (including a fragrance) must be identified. In some cases, the supplier of the mixture or fragrance may need to provide this information to the Agency. Prior to the Agency's receipt of an application, applicants must arrange with a proprietary mixture or fragrance supplier to provide the component information to the Agency or promptly upon EPA's request. If the inert ingredients in a proprietary blend (including fragrances) cannot or are not identified or provided within the 21-day content review period, the Agency will reject the application.

During the 21 day content review, applicants should submit information to the individual identified by the Agency when the applicant is informed of an unapproved inert.

Unapproved Inerts Identified on CSFs

All applications except conventional new products and PIPs

Once an unapproved inert is identified on a CSF, the Agency will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Provide the required information necessary to identify an inert approval application that is pending with the Agency; or
3. Submit the information and data needed for the Agency to approve the unapproved inert. If this option is selected and implemented, the Agency may request an extension in the PRIA decision review timeframe to accommodate the inert review/approval process;
4. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of these options is selected and implemented by the applicant within the 21 day content review period, the Agency will reject the application and retain 25% of the full fee of the category identified.

Conventional New Product Applications

When the Registration Division identifies an unapproved inert on a CSF with an application for a new product that the applicant has not identified as requiring an inert approval (R300 or R301), it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the inert's identity or CAS number, providing documentation that the inert has been approved, or removing the unapproved inert from the CSF or replacing it with one that is approved for the application's uses; or
2. Submit the information and data needed for the Agency to approve the unapproved inert, including any required petition to establish or amend a tolerance or exemption from a tolerance. (This option may change the PRIA category for the application, which could require a longer decision review time and a larger fee. If additional fees are due, they must be received by the Agency within the 21 day content review period.)

3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21-day content-review period, the Agency will reject the application and retain 25% of the appropriate fee for the new product-inert approval category.

PIP Applications

When the Biopesticide and Pollution Prevention Division identifies an unapproved inert on a PIP CSF and a request to approve the inert does not accompany the application, it will contact the applicant with the following options:

1. Correct the application by, for instance, correcting the spelling or name of the inert to that in 40 CFR 174, or providing documentation that the inert has been approved; or
2. Submit the information and data needed for the Agency to approve the unapproved inert. If an inert ingredient tolerance exemption petition is required, the petition must be received by the Agency and the B903 fee paid within the 21 day period. If this option is selected and implemented, the Agency will discuss harmonizing the timeframe for both actions.
3. Withdraw the application (the Agency retains 25% of the full fee for the fee category estimated); or

If none of the above options is selected and implemented during the 21 day content review period, the Agency will reject the application and retain 25% of the fee.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Biopesticide applicants are advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.

Kang, Ji Yeon

From: Georgia Anastasiou <georgia@lewisharrison.com>
Sent: Tuesday, October 17, 2017 4:07 PM
To: Kang, Ji Yeon
Cc: Ashe, Anthony
Subject: RE: Submission to EPA: Cleanburn (EPA Reg. No. 33025-A).
Attachments: 50389802_Data_PreliminaryAnalysis_rev_confstatement.pdf

Dear Joyce,

My apologies for the error. I corrected the confidentiality statement to claim no confidentiality. That is the only change I made to the attached study - I'm not sure if it is easier to extract the page or send you the entire study, so I attached the entire study just in case.

Sincerely,

Georgia Anastasiou
Lewis & Harrison, LLC
122 C Street, N.W., Suite 505
Washington, DC 20001
P: 202-393-3903 x 119 (Tu,W&F)
P: 240-442-2877 (M&Th)
F: 202-393-3906

From: Kang, Ji Yeon [mailto:Kang.Joyce@epa.gov]
Sent: Tuesday, October 17, 2017 8:52 AM
To: Georgia Anastasiou
Cc: Ashe, Anthony
Subject: Submission to EPA: Cleanburn (EPA Reg. No. 33025-A).

Dear Ms. Anastasiou,

My name is Joyce Kang and I am a contractor with the EPA. I am contacting you in regards to your submission in support of the product Cleanburn (EPA Reg. No. 33025-A). We have found a deficiency with the submissions that will need to be addressed:

1. For MRID 503898(02) 'Cleanburn: Preliminary Analysis Discussion,' when the claim is made that a study includes confidential business information, such information must be excised from the body of the study and confined to a separate Confidential Attachment. We cannot accept your claim that the entire text of the this study falls within the scope of FIFRA 10(d)(1)(A), (B), and (C).

Please send the revised study before Oct 30th so that we may further process your submission. After Oct 30th, please direct all correspondence/corrections to the appropriate EPA Risk Manager. If you have any questions, please do not hesitate to contact me.

Joyce Kang

[Bracketed Text] = Optional Language

Note: **Bold, italicized text is information for the reviewer and is not part of the label.**

CLEANBURN

EPA Reg. No. 33025-#

Master Label

CLEANBURN

Torch Fuel

[Alternate Brand Name: TIKI Brand Paradise In Your Backyard Clean Burn with Citronella]

Active Ingredient:

Oil of Citronella* 3%

Other Ingredients 97%

Total 100%

* Contains no less than 0.56% geraniol

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS: [1pt 2 fl oz/18 fl oz (532mL)] [1qt/32 fl oz (946mL)] [1qt 18 fl oz/50 fl oz (1.48L)] [2qt/64 fl oz (1.89L)] [3qt 4 fl oz/100 fl oz (2.96L)] [1 gal/128 fl oz (3.78L)]

Product of Singapore, Blended and Bottled in the USA
Lamplight Farms Inc.
W140 N4900 Lilly Road
Menomonee Falls, WI 53051-7035

EPA Reg. No. 33025-#

EPA Est. No.

020##

Read [Entire Label] [All Warnings] [Back Panel] CAREFULLY.

[KEEP OUT OF REACH OF CHILDREN AND PETS.] [NEVER LEAVE A BURNING TORCH UNATTENDED.] [FAILURE TO FOLLOW INSTRUCTIONS MAY RESULT IN SERIOUS INJURY OR PROPERTY DAMAGE.] [DO NOT DRINK.]

Batch code _____

Optional Marketing Claims - continued

- [No More Smoky Mess!]
- [[Create] [A] [Convenient] Paradise In Your Backyard]
- [For use in TIKI® Brand torches]
- [[For best results] Use in TIKI® brand torches]
- [For best results use several torches [around an area] [to surround an area] [throughout your backyard]]
- [[For best results] [properly] refill torch canister when it is 2/3 empty]
- [No Smoky Mess]
- [Traditional Tabletorch & Fuel]
- [Clean Burn]
- [TIKI® Brand Clean Burn System]

Questions or comments? Call 1-888-473-1088 [or visit our website at www.tikibrand.com.]

